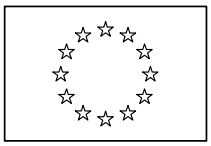

EUROPEAN COMMISSION

EU Priority Proposals

for Regulatory Reform in Japan

28 October 2004

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INTRODUCTION

The Regulatory Reform Dialogue is now ten years old. Over that period, and particularly in recent years, it has proved its worth as a systematic, but, non-confrontational way to address problem issues for our business community in doing business in Japan. Four important, but, non-exhaustive examples of progress to which the Dialogue has contributed in the Japanese market are the sharp reduction in the approval time for drugs and the rationalisation of the approval system; the legislative amendment allowing for free association between EU and Japanese lawyers; the continued strengthening of the capacities and activity of the Japan Fair Trade Commission; the general acceptance of international standards. Bearing in mind that the dialogue is a two-way process, fields where the EU has responded to Japanese requests include driving licences, data protection and implementation of the Community Patent System.

As well as being effective, the dialogue has been progressively made more efficient through a stricter prioritisation of issues, while remaining comprehensive through the use of priority and supplementary proposals. A closer association of the Member States with the Dialogue, a sustained commitment from the Commission services and strong efforts by the Japanese authorities to ensure participation by all the ministries and agencies concerned have together contributed towards this successful development. In fact, the EU/Japan Summit in June 2004 underlined the value of the Dialogue and recommended it be further streamlined.

Thus, the European Union once again thanks the Government of Japan for the opportunity to make a contribution, through the EU-Japan Regulatory Reform Dialogue, to Japan's rolling programme of regulatory reform. The EU hopes that its input will serve as a point of reference for the recommendations of the Council for the Promotion of Regulatory Reform (CPRR) expected at the end of this year, and that the Government of Japan will be able to take up as many as possible of the EU's proposals.

Despite the progress made to date, continued advance in regulatory reform in Japan is indispensable for a number of reasons.

A first important reason relates to the health of the Japanese economy itself. It is clear from the GDP statistics for recent quarters that Japan is pulling out of a long period of below potential growth and is moving into a phase of sustained expansion. Policies to promote a competitive market environment across a whole range of sectors, for instance financial services and transport, will be essential to help Japanese companies make the technical, financial and business adjustments necessary to support a sustained recovery and also to create better opportunities for the Japanese consumer in terms of range of choice of price and quality against a background of slow growth in household income.

Another reason for keeping up efforts in regulatory reform is the need to create an environment more conducive to investment and the growth of new businesses. This is true both for Japanese firms and for investors from the EU. The rate of new company start-ups in Japan, 3.8% in 2003, is still very low compared with other OECD countries.

The EU has warmly welcomed the new policy of the Japanese Government to increase substantially the amount of foreign direct investment in Japan. As a practical means of achieving this objective, Japan and the EU have agreed at the June 2004 summit an Investment Framework which will be implemented, inter-alia, through

mainstreaming investment related issues in the Regulatory Reform Dialogue – issues like predictability of administrative decision making affecting investment projects, improving flexibility in compensation for mergers and acquisitions and acceptance of test data.

The EU proposals are set out below. The EU would however, like to signal in this introduction three particular concerns.

First is the importance of implementation of reform measures once they are announced. An important example of this is the implementation arrangements for the recent legislation allowing free association between foreign and Japanese lawyers.

Second is consolidation of the good progress made in strengthening the Japan Fair Trade Commission (JFTC). In the view of the EU it is very important to carry through the proposed amendments to the Anti-Monopoly Act which will increase considerably the powers of the JFTC to deter violations of competition rules. Commissioner Monti in a recent press article in the Nihon Keizai Shimbun has set out the detailed arguments for the adoption of these legislative amendments.

Thirdly, and finally, the EU is particularly concerned at the lack of, or relatively little, movement in two important areas – transport and sanitary and phyto-sanitary rules including on food additives. This stands in sharp contrast to the progress in other fields. Achieving advance on these issues at the forthcoming High Level Meeting would surely be to the benefit of the ordinary Japanese consumer, would encourage tourism into Japan in line with government policy and would help our shared goal of boosting investment.

As a concluding point, the EU wishes to signal its satisfaction that in the course of bilateral discussions on regulation across a wide range of sectors, both sides have begun to focus on questions related to the quality of regulation and best international regulatory practice, having in mind the need to facilitate a smooth adjustment process in our economies and to encourage the diffusion of new business techniques and technological progress into wider economic activity. This new approach has been highlighted as a way forward in the Investment Framework. Promotion of dialogues on new regulations, improving regulatory transparency in the process and a forward looking attitude to cooperation on standards and conformity assessment are specific examples of what both sides want to pursue in this regard.

1. Continuing to improve the Investment Environment

The European Union welcomes the pro-active attitude of the Government of Japan in promoting Foreign Direct Investment (FDI). In his general policy speech on 31 January 2003, Prime Minister Koizumi announced his intention to make Japan an attractive destination for foreign firms and to double the cumulative amount of foreign direct investment in five years. His speech was followed by a report of the Japan Investment Council (JIC) on 27 March 2003 on further measures needed to increase FDI inflows.

In 2004, the promotion of FDI has remained a policy priority in Japan. The "Program for the Promotion of Foreign Direct Investment" (last updated on 19 May 2004) of the Japan Investment Council contains a number of items which are important for EU companies, in particular, improvement of the business environment (cross-border M&A), review of the earlier reform of administrative procedures (no-action letter, public comment procedure) and creation of favourable employment and living conditions (reform of labour market, entry and residence requirements).

In the context of bilateral EU-Japan relations, a "**Cooperation Framework for Promotion of Japan-EU Two-Way Investment**" was adopted at the 13th EU-Japan Summit on 22 June 2004. In this document both sides recognize that the steady improvement of the investment and business environment in Japan, the EU and its Member States is vital for the promotion of two-way investment.

The Cooperation Framework emphasizes the role of the high level Regulatory Reform Dialogue as a vehicle to address issues affecting the local investment and business environment. FDI has made most headway in Japan in sectors where deregulation has progressed (like financial services and telecommunications), suggesting that if regulatory reform and economic restructuring can be advanced on a broader basis in Japan, more foreign direct investment will follow.

The EU continues to regard the absence of tax neutral share-for-share swaps for merger and acquisition activities in Japan, the high cost threshold for investors there and the transparency and predictability of the investment environment as three key areas for active reform. In addition, relaxing rules concerning human resources would also contribute to improving conditions for existing investors and attracting potential investors from overseas.

1.1.Corporate restructuring and related tax measures

Tax-neutral share-for-share swaps, a common merger and acquisition (M&A) mechanism in other major markets, are not yet generally possible in Japan. This hinders the flow of foreign investment as foreign companies often prefer M&A to enter a new investment market.

As of 9 April 2003, the Law on Special Measures for Industrial Revitalization allows cross-border "triangular" mergers (foreign parent companies are entitled to use their shares through a 100% Japanese subsidiary when merging with/acquiring another Japanese company) if that Japanese company is in distress and if the company's "revitalisation" plan is approved by the Japanese Government. However, the Law fails to address taxation aspects, and thus the rules for qualified tax-neutral mergers are not applicable. In practice therefore, shareholders of that Japanese company are taxed on the unrealised capital gains when they exchange shares of the European parent company. While the possibility of triangular mergers provided for in the Japanese legislation is welcome, the fact that it is tied to a specific restructuring scheme and requires ministerial approval means that in practice, the use of this new

instrument remains limited. Moreover, the tax system makes the use of this scheme unattractive. As a result, up to now no foreign company has used triangular mergers.

The EU welcomes expected changes in the Commercial Code following the preparatory work of the Corporate Law Reform Committee that would allow **cross-border stock-for-stock mergers without pre-condition**, under the "triangular merger" formula. The EU urges the Government of Japan to follow the recommendation made by the Japan Investment Council in March 2003 to examine related tax measures and to ensure that the same **tax-deferral rules on capital gains** currently available for corporate reorganisations between Japanese companies are extended to cross-border stock-for-stock mergers. This is the only way to ensure a viable and attractive M&A market for foreign operations in Japan. By carrying out these changes in parallel to the revision of the Commercial Code, the Government of Japan can send a forceful signal to foreign investors that their engagement in Japan is indeed welcome.

The EU understands that METI has begun studying measures to help Japanese companies fend off takeover bids, e.g. by dilution of share capital and other **anti-takeover measures**. There is a risk that such strategies will be used by management to defend vested interests and will thus be detrimental to boosting corporate competitiveness. Such measures may not be necessary, given that the Commercial Code contains already quite stringent requirements for M&A, such as the need to obtain approval of two thirds of the shareholders of the target company. The measures envisaged seem primarily designed to strengthen the defence options of Japanese companies against cross-border M&A attempts and thereby offset the planned relaxation of rules in the Commercial Code on the forms of consideration which can be paid in mergers. It is difficult to see why the Government of Japan, on the one hand, embraces the benefits M&A brings to the domestic economy while, on the other hand, considering to raise barriers for cross-border activities of the same kind.

This is even more striking since figures for recent years show a remarkable **divergence between domestic M&A activities and cross-border deals**. Having averaged around 500 deals per year throughout much of the mid-nineties, the number of domestic M&A has increased fourfold since, to almost 2.000 deals in the year 2000 and thereafter. By contrast, the number of cross-border mergers has remained flat, and their value fell drastically after a short peak in 1999. This does not bode well for the achievement of Japan's objective to double the cumulative stock of FDI within 5 years.

The introduction of a **consolidated taxation system** in 2002 was most welcome and addressed a long-standing EU concern. The expiry, as of April 2004, of the 2% surtax levied on consolidated tax accounts also responded to an EU request. However, a number of issues remain to be addressed if the system is to deliver its full potential in promoting investment and corporate restructuring. EU 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 on entry to the consolidated group, and the obligatory integration of all 100% subsidiaries to be eligible for consolidation. Finally they request that local taxes should be included in the consolidation.

Priority reform proposals:

1. ***The EU recommends to the Government of Japan to further "mainstream" pro-investment measures throughout government policy-making. This could be achieved for instance by taking a broad cross-sectoral approach to investment***

under the Three-Year Regulatory Reform Programme, as well as in the work of the CPRR, and the "Program for the Promotion of Foreign Direct Investment in Japan" and the work of the Japan Investment Council.

2. ***The EU urges the Government of Japan to facilitate corporate restructuring and to allow tax-neutral share-for-share M&A by foreign companies in all cases.***
3. ***The EU would appreciate clarification concerning potential measures designed to make cross-border M&A more difficult by introducing anti-takeover measures.***
4. ***The EU urges the Government of Japan to address industry's concerns about the ability companies to make effective use of the consolidated tax system, and to:***
   a. ***Replace the requirement that only 100% subsidiaries may be consolidated by a 50% threshold.***
   b. ***Eliminate the expiry of pre-consolidation period losses of companies when they enter the consolidated group.***
   c. ***Eliminate the obligatory taxable revaluation of assets of companies entering the consolidated group.***
   d. ***Eliminate the obligatory integration of all 100% subsidiaries if a group wishes a consolidation.***
   e. ***Include local taxes in the consolidation. The taxation system related to Corporate Inhabitant Tax (hojin-jyumin-zei) and the Corporate Enterprise Tax (hojin-jigyo-zei) should be simplified as much as possible in order to reduce the administrative burden on companies in the preparation of related local tax returns.***

1.2 Transparency and Predictability

An area of continuous concern is the transparency and predictability of the regulatory process. Transparency means dissemination of, and access to, information or all interested operators in order to ensure fairness as well as economic efficiency. It is closely linked to the principle of legal security.

There has been significant progress in this area in recent years, the two most notable developments being the introduction in 1999 of the Public Comments Procedure, and in 2001 of government-wide guidelines obliging each ministry to set up a "No Action Letter" (NAL) system. The decision of the Cabinet of Japan of March 2004 to review the implementation of the "No Action Letter" system and the "Public Comment" procedure in Japan is encouraging.

The **Public Comments Procedure** is designed to allow all interested parties to comment on administrative measures and draft regulations. Significant improvements in the quality of consultation with regulatory authorities over recent years are reported by EU companies. The EU also welcomes the recent efforts, to introduce a 30-day period as the standard rule for all ministries and government agencies.

According to the latest annual report of the Ministry of Internal Affairs and Communications (MIC) released on 27 August 2004, a total of 501 public comment procedures took place in FY 2003, up 25.6% from the previous year.

The annual report pointed out that there were cases where the public comment procedures did not appropriately follow the Cabinet Decision. These included cases where public comments were not published (17 instances, or 3.4%) or published only after publication of the relevant rules (51 instances, or 10.2%). In more than 80% of all cases the draft cabinet orders or ministerial ordinances were **not** amended following the receipt of public comments. This gives reason to doubt whether the public comment procedure serves its proper purpose.

Judging from the way in which the system of public comments is run by the ministries and agencies and is used by the public, this system has taken root in Japan. The latest OECD report of 19 July 2004 identifies progress, but also states that effectiveness could be improved. According to this report, while ministries and agencies are complying with the letter of the procedure, there is too little time for well-substantiated comments to be taken into account. The EU is aware of at least one case where a regulation has been issued virtually on the day following the end of a public comment procedure.

At the time of the revision of the Regulatory Reform Programme on 19 March 2004, the Public Comment Procedure was reviewed and the 30 day period for comments became the basic rule as of 1 April 2004. Under the new system if such a period is set at less than 30 days, ministries are obliged to make public the reasons. On 5 April 2004, MIC called on ministries and agencies to respect the new rules. Despite these efforts, the available information suggests that only about half of all public comment procedures respected the 30 days minimum rule so far. In all instances of setting periods of less than 30 days, ministries failed to give the reasons.

The **"No Action Letter" (NAL) system** has the capacity to save companies time and money by giving advance guidance on planned business situations. However, the number of NAL issued since the inception of the system is still very limited (9 in FY 2001, 14 in FY 2002 and 20 in FY 2003). In order to bring its intended benefits, the system needs to be implemented in a pro-active and consistent manner.

Until now, each administrative body has established its own "No Action Letter" (NAL) guidelines. This leaves open the risk of inconsistent application in terms of criteria for receiving requests, including scope of application, and the degree to which a given ministry feels itself to be bound by its replies to requests.

Replies given by administrative bodies are not binding, thus giving rise to doubts about their reliability as the basis for major business decisions. It is obvious that every case needs to be treated on its own merits, and that a change of circumstances could always result in a different assessment. However, there is a legitimate expectation by business that similar cases should be treated correspondingly, and that precedents should provide a yardstick to assess the feasibility of planned business transactions. As mentioned during last year's dialogue, this kind of binding effect is recognised in European jurisdictions (e.g. "Selbstbindung der Verwaltung" in German administrative practice, based on Article 3(I) of the German Constitution). The EU notes that the OECD report from 19 July 2004 also contains the same recommendation.

With regard to the *kaito bunsho* system used by the National Tax Authority (NTA), the EU welcomes the changes introduced in March 2004 as a result of which taxpayers can now seek written clarifications on specific kinds of transaction and thereby obtain guidance regarding specific tax situations. The EU would welcome additional information on how these changes are being implemented in practice and whether there are plans to make such clarifications available to the public, in an

anonymous format, as a standard practice, in order to establish a written body of precedent.

Priority reform proposals:

1. ***With regard to the Public Comments procedure, the EU urges the Government of Japan to build on progress in implementation and to:***
   a. ***Enforce and monitor its use by ministries and agencies, and in particular ensure that the 30 days period is being applied effectively across all Ministries and Government agencies;***
   b. ***Ensure that ministries, agencies, and, where applicable, advisory councils, allow sufficient time properly to reflect considered public comments in draft regulations and reports. All public comments submitted should be published.***
2. ***With regard to the "No Action Letter" (NAL) system (and, similarly, the NTA's kaito bunsho system), the EU urges the Government of Japan to:***
   a. ***Monitor centrally the implementation of the system in order to ensure that consistent criteria for the receivability of requests, including scope of application, are applied; and***
   b. ***Make NALs binding on the issuing body.***
3. ***With regard to the NTAs administrative practice (kaito bunsho), the EU would appreciate information on how the changes of March 2004 are being implemented in practice and whether such clarifications will be made available to the public, in an anonymous format, as a standard practice.***

1.3 Human resources

Managing human resources effectively and securing good quality foreign employees are essential issues for foreign companies with an office in Japan. To this end, the current arrangements for foreign employees paying into the Japanese pension system has an adverse impact on business development and investment, as it obliges foreign employees to pay into the Japanese pension system, often without any prospects of receiving a benefit or a full refund at the time of their departure from Japan. This significantly limits the incentive for expatriates to engage in a professional activity in Japan.

All workers in Japan are required by law to pay into the Japanese public pension system. The particular pension scheme to which one belongs depends on the type of job that one holds. Most salaried workers pay into the Employees' Pension Insurance System (*kousei nenkin*) while self-employed individuals, students, retirees, etc, pay into the National Pension System (*kokumin nenkin*). Contributions to the Employees' Pension Insurance System are shared equally between employee and employer. In principle, workers collect benefits from the age of 65 so long as they have paid into the system for at least 25 years.

The Japanese pension refund system for departing foreign workers (*tanki zairyu gaikokujin ni taisuru dattai ichijikin*) was originally established to address complaints from foreign workers that the Japanese pension system was unfair to foreigners who did not intend to stay in Japan for longer than 25 years. A partial refund system was adopted into the Pension Law in 1994.

At present, foreign workers living in Japan who are not subject to a bilateral social security agreement must contribute to the Japanese pension system along with their employers. For foreigners leaving Japan that have worked in Japan for longer than 6 months and less than 25 years, it is possible to receive a partial refund of pension contributions, capped at 3 years and 1,488,000 yen. The EU notes that the upper limit of payments was raised in October 2004, and that the requirements for early leavers will be eased in October 2005.

While a number of bilateral Social Security Agreements with several EU Member States have been concluded, or are being negotiated at present, it would still take a considerable time at the current pace of progress before the problem of dual pension membership and wasted premium payments will be solved for all EU citizens. The EU suggests, therefore, that departing expatriates should receive a full refund of the actuarial equivalent of all mandatory pension contributions paid to date, or at least the period and the amount for the refund should be extended to 5 years in line with recent developments to extend the length of stay of certain foreign workers (e.g. those working in Special Zones for Structural Reforms).

It is recognised however, that regulations governing temporary workers have seen significant progress. Recent revisions to the Labour Standards Law have increased the number of job categories for temporary (or dispatched) workers, including jobs in the manufacturing sector. The 3-year limit on temporary employment has been eliminated for 26 different job categories, and the allowable employment contract period has been increased from one year to three years for others. The EU encourages Japan to pursue this process.

The EU also notes an urgent need to encourage foreign investment by relaxing residence and immigration rules and accelerating related procedures, such as visa rules, work permits and other stay-related requirements, including for transfers within companies. The EU supports the recommendations of the Japan Investment Council's (JIC) expert committee on this issue, notes the measures envisaged under the "Program for the Promotion of FDI in Japan" and would appreciate an update on the efforts to improve the situation.

<u>Priority reform proposals:</u>

1. ***Concerning pension schemes, the EU encourages the Government of Japan to***
   a. ***Conclude bilateral social security agreements with all EU Member States as soon as possible.***
   b. ***Increase the cap to 5 years as a first step towards allowing for a full remittance of the actuarial equivalent of mandatory contributions to the Japanese public pension system to departing expatriates..***
   c. ***Make contributions to foreign-based pension plans subject to the same tax relief as contributions made to pension plans in Japan.***
   d. ***Improve the defined-contribution (DC) pension scheme by increasing tax-exempt contribution levels, allowing matching contributions, and allowing plan-holders to borrow against their pension reserves.***
2. ***Concerning the rules and procedures related to immigration and residence status further relaxation should be considered.***

2. Promoting more competitive markets

2.1. Government procurement

The EU welcomes the continuation of the current bilateral dialogue on Government Procurement and appreciates the explanations provided by the Japanese Government which help the European Commission and EU companies better understand the functioning of the government procurement system in Japan in general and the public works / public construction sector in particular.

The EU continues to believe that there is scope for improving the Japanese public procurement system, in particular as concerns the procurement of construction and public works. The EU has recently revised its procurement system and introduced simplified rules aimed at boosting competition among bidders, reinforcing transparency and ensuring more innovative solutions in particular for complex projects. The EU would like to share this experience with Japan and, in turn, draw some new conclusions on how to encourage the participation of EU bidders in public works projects in Japan.

The Japanese public works market remains attractive to EU business, in terms of the number of business opportunities and its aggregate value. EU companies succeed in winning contacts to deliver public works projects for governments and public entities worldwide, but the EU market share in Japan remains insignificant. The EU appreciates the Japanese Government's openness to discuss this situation. The EU recommendations (below) are intended to contribute to improving government procurement legislation and practice, with a view to encouraging foreign participation, boosting competition and ultimately reducing budget expenditure and obtaining better services and more foreign investment.

At the autumn 2003 High Level Meeting of the Regulatory Reform Dialogue, Japan and the EU conducted an intensive dialogue on the business evaluation system (keishin) which the EU considers a deterrent for EU companies in accessing the Japanese market. On the basis of that exchange of information and views, the EU would like to enter into a more constructive phase by submitting specific recommendations on the business evaluation system. A first set of general recommendations regarding the business evaluation system are listed below. The EU looks forward to a constructive dialogue aimed at formulating possible proposals to amend the system.

Although the Ministry of Land, Infrastructure and Transport's (MLIT) system of certification of foreign experience and the price-ceiling system were raised at the 2003 discussions, the EU would like to receive a comprehensive explanation on the functioning of both procedures. The paragraphs below outline the EU's understanding of the procedures and explain why these may deter EU participation. In particular, the EU would like to extend the discussion on price-ceilings to the incidence of bid-rigging cases and the beneficial impact a change in the price ceiling practice might have on such illegal business practices.

The EU notes Japan's interest to increase the participation of Japanese companies in the EU public procurement market. We would be pleased to discuss the EU system in the context of this dialogue.

The EU proposes to comment on the following elements of the Japanese procurement system:

1. MLIT's certification of foreign experience

The EU considers that the two-step system, i.e. foreign experience can be recognised only after obtaining certification by MLIT prior to the bidding, is potentially discriminatory and a deterrent for foreign bidders. In the EU system, foreign experience is evaluated by the procuring entities on an equal footing with domestic experience. In the EU practice, foreign companies are entitled to present their technical capacity and other requirements according to the law of place of establishment.

2. Business evaluation (Keishin)

The EU considers that the business evaluation takes too long to allow companies to participate adequately in a *particular* tender after publication of a tender notice. Article XI of the WTO Agreement on Government Procurement provides for a minimum 40 days delay for the receipt of tenders from the date of publication of a tender notice. The EU understands that it is in many cases impossible to go through the business evaluation process within this time frame.

As a consequence, the EU is of the view that this mechanism has a disproportionate effect on potential tenderers as they are prevented from applying for a particular procurement until they have the results of the Keishin evaluation. Moreover, the capacity of a tenderer is likely to evolve depending on its growing experience and activities. A one-off assessment can not reflect this evolution appropriately. Lastly, the EU is of the view that procuring entities, when launching a procurement are the best suited bodies to determine the level of capacity necessary for each procurement in question.

The business evaluation score is the result of a global assessment of financial and technical abilities. The problem is that there is no minimum level required for each specific ability. EU companies report that companies with very low financial ability obtain a rather high business evaluation score because the poor financial ability is "compensated" with a strong score on technical ability, such as the number of engineers or total staff, past experience, etc. The business evaluation would better reflect the real financial and technical situation of a company by requiring a minimum level for each required element. Companies could be required to present at least X million net profit or a minimum solvability ratio, or a maximum debt/equity ratio, etc.

3. Compulsory registration before each procuring entity

In addition to the business evaluation, companies are obliged to register with each procuring entity and pay an annual fee. The EU considers this requirement as unnecessary and burdensome. All the relevant information is either provided through the business evaluation or with the submission of the tenders.

4. Price-ceilings (yotei kakaku) and bid-rigging

Procuring entities in Japan often calculate a ceiling price (*yotei kakaku*) aiming at preventing a price escalation and to help in the tender evaluation. This price ceiling is kept in secret. This system is provided for in Article 29 of the Accounting Law and Article 234 of the Local Autonomy Law. The ceiling price is the upper limit for a successful competitive bid for public works, and if there is no bid with a price lower than that figure, the tender fails. The system also applies to minimum price system where, in case of an unusually low price, the possibility to perform the contract at that price is assessed. Local entities do not conduct an evaluation of performance in cases

of abnormally low bids, but set a minimum low price below which any tender is rejected.

The price reference system or price ceiling do not always takes account of new technologies or price advantages brought by foreign companies. Sometimes these innovative systems or technical advantages which are reflected in lower prices.

The price ceiling system may also favour leaks and bid-rigging, distorting the whole tender process. The fines imposed on several companies in recent months confirm the existence of bid-rigging practices in Japan. While judicial action and the government's determination to prosecute these criminals are one way to respond, a reform of the system itself would contribute substantially to discourage this practice.

EU procuring entities do not use price ceilings, although they may publicly announce the budget available for a given project. Such a practice in the EU prevents entering bids with a price over the available budget and adjusts the bids to available public funds. Regarding abnormally low bids, the EU procurement system allows for this possibility and calls for an examination of the reasons for abnormally low prices rather than a simple rejection of lower bids.

5. Technical specifications

EU companies report that technical specifications are often too narrow and do not allow bidders to bring any added value or innovative solution. In this context, the EU reminds Japan that Article VI of the GPA requires that technical specifications be set in terms of performance rather than design or descriptive characteristics. Moreover, requirements for or references to a particular trademark or trade name, patent, design or type, specific "origin, producer" or supplier are not permitted unless words such as "or equivalent" are included in the tender document.

The EU considers that technical specifications drawn up by Japanese procuring entities need to allow government procurement to be more opened up to competition. To this end, it must be possible to submit tenders which reflect the diversity of technical solutions. Accordingly, it must be possible either to draw up the technical specifications in terms of functional performance and requirements, or, where reference is made to the national standard, tenders based on equivalent arrangements/solutions must be considered by procuring entities.

Thus, to demonstrate equivalence, tenderers should be permitted to use any appropriate form of evidence and procuring entities must be able to provide a reason for any decision that equivalence does not exist in a given case.

In this context, the EU would appreciate receiving some information about Japan's policy on green procurement of goods as required by the *Policy for the Promotion of Eco-Friendly Goods and Services* and the *Law Concerning the Promotion of Procurement of Eco-Friendly Goods and Services by the State and other Entities.*

6. Transparency

In accordance with Japan's Action Programme on Government Procurement of 1994, MoFA organises an annual briefing on Government Procurement. The EC welcomes this initiative that provides more transparency, predictability and facilitates the participation of foreign bidders in Japan. The EU regrets*, however,* that the annual briefing on Government Procurement does not cover public works and public construction.

Priority reform proposals:

a. ***In addition to the MLIT certification system, the EU recommends allowing a 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 introducing into the business evaluation system a minimum indicator for some key financial and technical abilities. The EU recommends eliminating the obligation for companies to go through the business evaluation prior to any tendering and to allow procuring entities to themselves evaluate companies' ability during each procurement procedure.***

c. ***The EU recommends eliminating the compulsory registration or replacing it with a centralised registration at MLIT, valid for all procuring entities nationwide.***

d. ***The EU recommends suppressing the current price ceiling practice or to replace it by a mechanism similar to the one applied in the EU, i.e. indicating the earmarked budget for a given contract. In any case, abnormally low priced tenders should not be automatically rejected. Instead, tenderers should be given the possibility to justify and explain the reasons for such a low price tender.***

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

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

f. ***The EU recommends putting all the list of planned procurement during the fiscal year (which are distributed and explained by all ministries in the government procurement seminar), onto the website of MoFA / MIC for the information of companies not established in Japan and wishing to participate in public procurement.***

The EU recommends expanding the scope of this seminar to cover all infrastructure projects to be carried out during the fiscal year.

2.2. Information society

The EU notes that in 2004, Japan has started to initiate proposals for reforms in the ICT sector and in particular on interconnection, frequency allocation, as well as for the establishment of a new framework to carry out assessments of the state of competition. The EU welcomes these initiatives, but, considers that some of the proposals still need to materialise concretely before a final assessment is made since some aspects of the proposals remain a matter of concern.

Overall, the EU notes that interconnection charges in Japan are still significantly above international benchmarks. Against this background, one of the positive aspects of MIC's proposals relates to the progressive removal of non-traffic sensitive elements for the calculation of interconnection charges since it could contribute to the improvement of competitive conditions in Japan for fixed services. The removal of

NTS elements was requested by the EU last year. Nonetheless, the positive side of this would be nullified in the case where such a recovery of NTS elements would be borne by NTT's competitors.

On the proposed basic policy of September 2004 to conduct an assessment of the State of competition in the Telecommunications sector, the EU considers that it is a first important step to address its long standing request with a view to improve transparency and predictability of both rules and procedures in order to remedy anti-competitive situations. Nonetheless, the final outcome of the proposed framework remains to be clarified on the aspect of the relationships between political measures, the state of competition in a relevant market and business policies to remedy anti-competitive situations effectively. The adequacy and the efficiency of such a proposed framework will be benchmarked against its effective enforcement to maintain a level playing field in the Japanese telecommunications market.

On the management of frequency spectrum, the EU understands that the proposed changes are necessary follow up of the adoption of the new Radio Law last May. Nonetheless, some aspects of the newly proposed system for frequency allocation still remain to be clarified. The EU also shares the view that the present system of fees in Japan is outdated and is counterproductive in encouraging efficient spectrum usage. The EU will closely monitor the proposed developments in these fields.

More controversial, are the proposals based on the Frequency Reorganization Plan announced by MIC in October 2003 to raise the level of performance from the 2nd Generation to the 3rd Generation mobile communication system (IMT 2000) in the 800 MHz band. If as stated, the objective is to ensure compatibility with other countries, the proposal should consider multiple options for the assignment of spectrum instead of focusing only on the 800 MHz band. This point is explicitly recognised but no corresponding proposal has been made. The need to upgrade mobile communications systems from 2G to 3G is clear, but additional frequency spectrum should be based on future requirements expressed by all 3G operators. Therefore, frequency allocation should be made on a competitively neutral basis instead of automatically re-allocating the 800MHz spectrum to DoCoMo and to KDDI. Against this background, the proposed allocation would distort competition and discriminate unfairly against other providers.

On technological neutrality, the EU considers this principle to be crucial in the current context of ICT convergence. This convergence process is driven by a rapid development of both technologies and markets, thus overcoming the need for a technology specific regulatory framework. The recent developments of IP services and TV over ADSL implying radical changes in pricing strategies for carriers as well as a new approach to the regulation of broadcasting services, are probably the best examples of this trend. Consistent with its requests made last year, the EU continues to believe that the implementation of a flexible and technologically neutral regulatory framework is the most effective way to ensure that the same rights and obligations can apply to designated carriers in all market segments in order to prevent regulatory distortions impeding market entry.

Moreover, the EU failed so far to receive evidence that the regulator is independent and not accountable to any service suppliers. The issue at stake here is a risk of an inappropriate mixing of industry promotion and regulatory oversight. Similarly, no detail is given by Japan on how the notion of joint dominance could be addressed in the regulatory framework in Japan. The EU takes note of the reply made by Japan on these aspects, but is disappointed since it falls short of bringing concrete answers on how these problems are addressed and thus prevents the EU's from lifting its regulatory reform proposals.

SDoC (Supplier's Declaration of Conformity) was introduced in the EU in 2000 in the whole market of radio and telecommunication equipment (in excess of €100b in value) after the adoption of the R&TTE Directive in 1999. As a result access to the European market for the Japanese industry was largely facilitated. The EU therefore welcomed the introduction of a new system by the Japanese Government based on Supplier's Declaration of Conformity at the beginning of 2004 which give European industry equally advantageous market access procedures on a comparable basis.

However, the EU is disappointed that this system has been limited to wired telecommunication terminals, with only a limited application to wireless/radio equipment. A continued application of type approval with the obligation to have products certified again by a third party is no longer necessary, given the development of state of the art product design and the low risks associated with Radio and Telecommunication products. Experience in the EU with the Directive confirms that such procedures nowadays are no longer necessary.

It is planned to submit to the Diet a bill that would ban sales of prepaid mobile phones. The justification of this proposal is to prevent criminals from using "anonymous" mobile phones.

The present legislation requests people purchasing prepaid mobile phones to prove their identity to the phone retailers, but is seems that enforcement of this rule has been lax. Therefore a stronger enforcement of the present rules appears to be an appropriate tool to avoid criminal use of phones and the ban of prepaid phones is not necessary to achieve such aim.

Priority reform proposals:

a. ***The telecommunications regulatory authority should be fully independent from business suppliers, impartial, and dedicated to the promotion of competition in the Japanese market. It is important that the legislative texts show clearly that the regulator is only in charge of regulation (promotion of competition, universal service, licensing …) and does not interfere in the management of an operator. The EU therefore considers that the NTT law should be repealed since all necessary regulatory controls should be carried out on dominant suppliers or providers of universal service pursuant to the Telecom Business Law (amended accordingly) and State/Public Sector shareholder's must not be treated in the telecom sector differently from that in other sectors.***

b. ***The application of the LRIC model on interconnection should be reviewed in order to correct the misallocation of non-traffic sensitive (NTS) elements which result in higher costs for NTT-E&W's competitors. Similarly, the settlement mechanism which was established to compensate the potential losses of revenues incurred by a reduction of traffic should be abolished. Consistent with the EU's regulatory proposal made last year, the revision proposing the exclusion of NTS elements from the cost model, while basing the calculation on the most recent traffic data, is fully supported by the EU. Moreover, NTT-E&W should be required to absorb fully NTS elements and be allowed to recovers its costs from retail services provided over subscriber lines in order to prevent that NTT's inefficiencies are passed on to its competitors. Such a removal of NTS elements should take place within a one year period with a view to avoid any further market distortions such as are experienced now.***

c. ***Establish a technologically neutral regulatory framework for electronic communications services so that designated carriers operating services in the***

local and/or long distance wire-line markets as well as in the wireless market should be subject where appropriate to the same rights and obligations, notably in relation to the prevention of anti-competitive conduct and interconnection. Indeed, the designation of dominant carriers should be made possible in all service markets (including the long distance wire-line market) on a technologically neutral basis. It should be based on the ability to affect terms of participation in the market and not on specific criteria set a priori. The EU considers that, the basic architecture of the current regulatory framework in Japan for the regulation of designated carriers (apart from the fixed wire-line market), is still not based on transparent, objective and non-discriminatory criteria. All tools to correct market failure should be made available by law for dominant operators in any relevant market, and the law should not* a *priori distinguish between technologies in that respect. Regulatory measures to correct market failures should address effectively such failures. To this end, the proposed framework for the assessment of competition remains to be clarified in regard to the aspects of the relationships between political measures, the state of competition in a relevant market and business policies to remedy anti-competitive situations effectively.

d. ***The notion of joint dominance should also be recognised in Japan's regulatory framework as it is currently not so recognised in the revised TBL.***

e. ***Wholesale and retail tariffs notification requirements should be maintained for carriers with significant market power and/or having control over essential facilities. The last revision of the TBL, by lifting the obligation of Type I designated carriers to file tariffs for wholesale and retail prices prevents the regulator from monitoring the pricing conduct of the dominant carriers and to ensure that they do not engage in predatory pricing behaviours. Pursuant to the new revised framework in Japan, Type I designated carriers could thus for instance discount selectively in order to damage their competitors, or enter into price squeeze strategies. The EU understands that tariff notification and accounting separation obligations will continue to apply for services categorised as "Universal Services" for all operators including non-dominant operators.***

Consistent with the principles of asymmetric regulation and proportionality, the EU considers that these obligations should be lifted for carriers which are either non-dominant or not selected as universal service providers since it impacts their ability to compete effectively against designated carriers and causes them to incur undue cost. It also involves unnecessary procedures to the detriment of a fair and effective competitive environment.

f. ***Universal service should be adequately implemented, only where necessary, in order to address costs that are not covered by normal commercial practice. The objective of getting uniform rates nationwide in Japan should be achieved through the establishment of a universal service fund and should, in particular, fulfil the principles of transparency, non-discrimination and competitive neutrality. The EU fully recognises that maintaining uniform rates throughout Japan is politically sensitive but considers inappropriate that this objective be achieved through the use of interconnection charges as is currently the case. The cost of providing universal service to ensure uniform rates nationwide (including in less profitable areas) should instead be based on LRIC while the benefits of providing universal service (network externalities, brand name and presence) should be fully taken into account in the computation of costs. The current averaging system between NTT-E&W is a matter for concern since it***

leads to cross-subsidies between NTT-East and NTT-West, although the two companies are structurally separated and in principle prevented from entering into such practices through the imposition of competitive safeguards to ensure an adequate separation of their accounts. As a result, interconnection charges are also no longer cost-oriented. This is in breach of the cost orientation principle as provided for in the GATS/WTO Reference Paper.

g. Additional spectrum allocation for the additional IMT-2000 bands for 3G mobile communication systems should be made on a competitively neutral basis to prevent discrimination, and in line with agreements reached at World Radiocommunication Conferences. To this end, the proposal for future assignment of frequency spectrum should thus consider multiple options (such as 1.7 GHz) instead of focusing only on the 800 MHz. Additional frequency spectrum should be based on future requirements announced by all 3G operators. Therefore, the current proposal to re-allocate automatically the 800MHz spectrum to DoCoMo and Au KDDI should be abandoned since it would distort competition and discriminate unfairly against other providers.

h. In order to comply with its obligations under the TBT agreement to render market access regulations as least trade restrictive as possible, Japan should consider extending its SDoC (Supplier's Declaration of Conformity) system to all types of radio equipment as well. By doing so, Japan would set a precedent for other economies in facilitating market access for such products. This would benefit both Japanese and European manufacturers.

i. The EU opposes any proposal aiming at the ban of prepaid mobile phones. Such phones exist worldwide and a proper identification of the clients allows the identification of users as reliably as in the case of subscription. Also, prepaid mobile phones play a social role, since they permit the use of such devices to the lower income part of the population.

2.3. Financial services (banking, insurance, securities)

The EU has over the last five years intensified its efforts to promoting an open and competitive capital market in order to strengthen economic growth, offer consumers and investors greater choice at lower costs, and bolster the competitive dynamism of the global financial industry while ensuring sound regulation. It has moved rapidly forward with its Financial Services Action Plan (FSAP), aimed at achieving a uniform legal framework for an integrated EU-wide capital market. Equally, the Japanese Government has made important improvements to the Japanese financial sector in order to reform and revitalise it, which is strongly welcomed by the EU.

Important lessons can be learnt from the last five years of the FSAP, and these lessons are not limited to the European experience but have a wider significance including for Japan. European and Japanese financial institutions and markets are likely to become more – not less – interdependent in the coming decade. Market dynamics will force further adjustments both from regulators and supervisors in both regions. Old ways of organising financial supervision will continue to be called into question, and cross-border risk transmission will continue to turn national problems into international conflicts affecting the EU and Japan.

Based on the EU's own extensive experience in this field, we would like to address three areas where continued reform efforts should be vigorously pursued by the Japanese Government in order to build a more efficient financial system, reduce

prices for private and corporate consumers, and stimulate economic growth and job creation:

1) Transparency and simplification of regulatory and supervisory activities in Japan

Transparency and consultation with all concerned stake-holders are essential for efficient regulation and supervision. Stream-lining of procedures, consistent and impartial implementation of legislation, and simplification of the overall regulatory burden imposed on companies additionally contribute to creating a predictable, stable and favourable business environment conductive to economic growth and increased investment. We encourage Japan to commit itself to these principles, including in relation to third country regulators and companies.

The introduction of a "no-action letter" system is clearly a step in the right direction but the EU would encourage a more effective use of the system.

2) Continued reform of the Japanese financial environment

One major concern for European financial firms is the restriction on activities resulting from the Securities and Exchanges Law (art. 65). Under these rules, a lending and deposit bank cannot conduct securities or insurance business. There have been some relaxations of this rule but the firewalls required create barriers for foreign companies to offer financial services on an integrated basis.

The Japanese Government has indicated its intention to completely deregulate the distribution of insurance products through banks and other institutions within three years. While this step is warmly welcomed by the EU, it would encourage the Japanese Government to introduce the necessary changes as soon as possible without waiting until the end of the envisaged three year period.

3) Establishing a level playing-field

Insurance business managed by co-operative societies (kyosai)

In addition to the priority reform proposals raised by the EU in conjunction with Japan Post, we would also like to draw the attention to the insurance business managed by the kyosai. Mutual aid associations are becoming an increasingly large presence in the insurance market. The insurance premiums received by kyosai make up roughly 20% of the total premium revenues in the life and non-life sector.

Not only public sector entities such as kampo (Japan Post life-insurance) but also co-operatives should be subject to the same requirements as private insurers in order to create a level playing field in the insurance market.

Since kyosai provide the same service as their private-sector competitors, they should be subject to the same legal and regulatory requirements, that is, the same capital, solvency margins and policyholder protection funding requirements.

Policyholder protection fund

While the basic objective of protecting the consumers of life and non-life insurances through a policy-holder protection fund is without dispute, the requirements for all companies - regardless of their potential risk to policyholders – to contribute to the fund imposes a financial burden on those companies who have managed their business prudently and protects unfairly those business who have failed to ensure the interests of their consumers.

The EU would encourage the Japanese Government to immediately launch the long over-due review of the fund system with a view to ensure that only firms whose policyholders are protected by the system should have to contribute to it, since the

best way to ensure a high level of consumer protection is through effective prudent macro-level supervision.

Trust banking

The need to establish a level playing field does not only apply to private and public entities, however, it also applies to foreign and domestic companies. One such difference in treatment relates to trust banking where foreign banks suffer a competitive disadvantage. Recent reforms to the Trust Business Law expected to be adopted by the Diet will expand the types of property that can be placed in trust and expand the types of corporate entity that may engage in trust business. In our understanding, these reforms will not apply to foreign bank branches.

<u>Priority reform proposals:</u>

1a. In the banking and asset management areas, rules and regulations should be applied more consistently and the overlap of functions between regulators and self-regulatory organisations should be eliminated. The overall burden of reporting requirements to these various bodies should be stream-lined.

1b. In the banking area, confidentiality and the integrity of the inspection and penalty process must be ensured and the penalty should be commensurate with the violation.

1c. Most major financial markets allow asset managers to place orders in domestic markets on behalf of overseas group affiliates. In Japan this is not possible without a securities business licence. This is an impractical solution for asset management firms given the costs involved in setting up the necessary firewalls. The Japanese Government should revise the Investment Advisors Business Law to allow asset managers licensed in Japan to place orders to buy or sell Japanese securities on behalf of group affiliates.

1d. A more effective use of the no-action-letter should be ensured by FSA.

2a. The EU renews its request to allow financial institutions to undertake the full spectrum of activities e.g. banking, insurance and securities activities. This should be accompanied by the necessary administrative requirements to ensure a sound integrated financial industry in Japan. The provisions of Article 65 of the Securities and Exchange Law which prohibit integrated management of banking and securities businesses should thus be abolished.

2b. The complete deregulation of the distribution of insurance products should be done as soon as possible without waiting three years.

3a. Kyosai should be made subject to the same regulatory regime as licensed private sector insurers, and should refrain from taking advantage of their privileged regulatory and taxation position to develop new underwriting activities.

3b. The EU urges the Japanese Government to immediately launch the long over-due review of the Policyholder Protection Fund system with a view to ensure that only firms whose policyholders are protected by the system should have to contribute to it.

3c. No difference should be made between foreign and domestic branches as regards trust banking in that foreign bank branches in Japan should also be able to engage in trust and banking businesses concurrently.

2.4. Postal services- Japan Post

The EU welcomes the recent bold and ambitious postal privatisation initiative taken by PM Koizumi and the basic principles set out in the plan by the *Council on Economic and Fiscal Policy (CEFP)* for the privatisation of Japan's postal business. These steps are in line with a world-wide trend towards modernisation and market opening and they will enhance the overall efficiency of the Japanese economy. Unleashing such a giant as Japan Post onto the market, requires much consideration to the way this is done, and to the effects it causes. The legislator must play a key role in this process by ensuring that the transition is done as smoothly as possible, both for Japan Post but also for its private competitors, while at the same time ensuring that the market is not disrupted or distorted. The overriding objective should be to create a level playing field, which will be beneficial for all market players, the consumers and for the Japanese society as a whole. Against this background, there are three interrelated issues, which concern the core business of Japan Post and which will remain valid both during the transition period and in the post-privatisation phase:

1) Postal services

In order to ensure a successful outcome of the restructuring and partial privatisation of Japan Post, its various successor corporations need to be placed under equivalent supervisory control as is applied to its competitors. As in the EU and amongst the other OECD countries, Japan should also ensure that the regulator is independent and separate from the operators. This is good governance and ensures that conflicts of interest are limited, thus creating a level playing field for all operators. The *Basic Policy on Postal Privatisation* does not seem to make it clear which entity will be responsible for regulating and overseeing the *Post-office Network Corporation for Over-the-Counter Services* and the *Postal Delivery Corporation*, while the State is suggested to retain 100% ownership of the privatised entities. The EU would suggest establishing a clear separation between the regulator and the owner by establishing an independent regulatory authority, if indeed the intention in the *Basic Policy* is that MIC continues to be the regulator and a de facto stakeholder.

In addition, for areas open to competition but where a universal service obligation applies, the new operators should not have obligations imposed on them which go beyond what is necessary to ensure the universal service. Obligations which would be too burdensome could indeed hamper or even prevent competition by deterring operators from entering the market. In order to enable competition any Universal service obligation for competitors should be reduced to the minimum necessary because in the short term, they may not be able to meet the complete range of obligations. In order to give market entrants a better chance, it would be useful to have a non discriminatory, transparent and proportionate market access scheme based on objective criteria which imposes a limited range of obligations for essential requirements (confidentiality of correspondence, security of the network as regards the transport of dangerous goods and where justified, data protection, environmental protection and regional planning) if competitors wish to work in the Universal service area. There should be no universal service obligations imposed on competitors which intend to work outside of the fixed Universal service area. New services and higher added value services like Express services should not be considered as part of the Universal service area simply because Japanese Post is also acting in this area. In order not to distort competition, there should be no cross-subsidisation from non related economic activities like financial services or from the reserved area except what is strictly necessary to ensure Universal service obligation. Separate accounting of the different economic activities including reserved and unreserved areas is

essential in order to enable the independent regulator to control these activities (of the universal service provider) and thus ensure fair competition

2) Life insurance (kampo)

The EU warmly welcomes that the *Basic Policy* endorses the principle of "ensuring equal footing between the postal businesses and the private sector". Additionally, we also find it of utmost importance that the policy states that just as private firms, the postal businesses will have their government guarantees abolished, will be required to pay taxes, and will be required to make payments into government depositor and policyholder guarantee funds.

The EU would still, however, like to raise a few concerns.

- The Basic Policy states that expansion of the postal businesses into new business areas should be actively pursued and without any constraints. It remains unclear when, and to what extent, the *Postal Insurance Corporation* will be permitted to introduce new products in competition with the private sector.

- The Policy does not clarify whether the new *Postal Insurance Corporation* will be subject to supervision by Japan's Financial Services Agency, which oversees private insurers, either during the transition phase or in the post-privatisation phase.

- Notwithstanding the fact that the Policy stipulates that at the end of the transition period the *Postal Insurance Corporation* will be fully subject to the *Insurance Business Law*, the report recommends that certain exemptions be considered for the transition period. This may mean that during this period, the Corporation may not be fully subject to the same rules and disciplines as private firms.

- The envisaged holding company structure and the creation of the *Public Successor Corporation* to own the existing contracts of postal savings and postal life insurance, as well as the intention to let "profits and losses….revert to the new corporations" raise concerns about possible cross-subsidization between the various postal businesses and allows the government-supported benefits arising from the old structure to filter into the new corporations.

The EU also welcomes the opportunity opened up to investment advisors to submit their tenders for managing the existing yucho and kampo funds. We welcome this step to allow Investment Advisory Companies (IAC) access to managing these funds. However, practical rules on how the selection of IACs will be done have not yet been made public.

Priority reform proposals:

1. In order to establish a level playing field, the Government of Japan should ensure that the same supervisory structure is applied to the new corporations and private operators. A new independent regulator for postal services, which is separate from MIC, should be established. In addition, for areas open to competition but where a universal service obligation applies, new operators should not have to meet obligations which go beyond what is necessary to ensure universal service by the Universal service provider Japanese Post. Separate accounting of different activities is necessary so that the independent Regulator can prevent cross-subsidisation and ensure transparent market entrance schemes.

2a. The EU regrets that during last year's Regulatory Reform Dialogue meeting, kampo's application for introducing a new product in the life-insurance sector was accepted. Thereby, these so called fixed-term whole-life insurance policies were for the first time allowed to compete with core private-sector products.

Kampo should not be allowed to use its privileged position to further expand into new product areas during the transitional period and until a level legal and regulatory playing field is established.

2b. In order to ensure a level playing field, the new corporations should be subject to the same supervisory structures and legal and regulatory requirements as the private sector.

2c. Cross-subsidisation should be rendered impossible and the new corporations should not be in a position to benefit financially or otherwise from the close structural link with the Public Successor Corporation. The possibility for all concerned parties to appeal any breach of this principle should be made available through independent review by the supervisory authority(ies) and an open and transparent appeals procedure.

2d. We would encourage Japan Post to ensure that the forthcoming selection process for IACs is based on objective and transparent criteria in order to ensure open and transparent competitive tendering.

2.5 Transport

2.5.1 Air transport

International air transport links the European and Japanese economies; close cooperation in this important area is in the interest of both sides, and of their citizens. Japanese and European regulators have a role in promoting best practices in relation to security, safety and consumer protection. Nevertheless, there is a real risk that inappropriate regulation can impose unnecessary constraints on the market, leading to economic inefficiencies. At the same time, in other cases, regulatory intervention is necessary in order to ensure satisfactory operation.

We have consulted widely with European economic operators in preparing for this year's Proposal; and are satisfied that while much has been achieved in the last years, more may be achieved.Airlines have to make significant efforts to maintain existing services at a satisfactory level of profitability. In the current difficult business climate, the Japanese authorities have a role to play in helping to modernize air transport facilities and the regulatory framework, in the interest of users and consumers alike.

Only in this way will international airlines be able to contribute to the Japanese Government's stated goal of doubling the amount of tourists visiting Japan before the end of the decade.

General comment: question of competence

The replies prepared by the Japanese authorities in connection with last year's Proposal were helpful and informative. Nevertheless, on one issue, there appears to be some misunderstanding. Due to internal legislative change within the European Union, the European Commission is now empowered to speak on behalf of the EU Member States in relation to a large number of aspects of civil aviation. The European Commission addresses certain problems in this field, with the knowledge and approval of our member States. The EU does not have exclusive competence in the field of civil aviation. This is why – as Japan correctly noted last year – discussions continue to take place between the Japan Civil Aviation Bureau, and counterpart authorities in EU member States, concerning air traffic rights and other issues. All bilateral air service agreements, however, must be in conformity with the requirements of EU law; and member States have been consistent in expressing this view to partner countries with which they have negotiated. The European

Commission would welcome the opportunity in the near future to provide fuller explanations to the appropriate Japanese authorities of what recent jurisprudence and legislation mean; what changes are likely to be required in relation to existing legal agreements between Japan and EU Member States; and the manner in which such changes may be made.

Airfares

The distribution, pricing, and settlement of international airfares are subject to significant regulation in Japan. Airlines have limited freedom to sell their products and services directly to consumers in a transparent fashion (including over the Internet), as has become common in other OECD countries. In Japan, airlines are allowed little or no flexibility to advertise and sell fares for international travel to and from Japan at rates other than those officially approved by IATA. As the rates set by the IATA do not accurately reflect current market conditions, most individual fares sold in Japan are repackaged all inclusive discount fares sold through licensed travel agents. This places European carriers at a distinct disadvantage, as they do not have the economy of scale to set up their own de facto direct distribution channels through captive agencies and affiliated travel offices, and therefore have limited control over the final consumer price.

The EU appreciates the efforts of the Japanese authorities to deregulate the sale of advance-purchase fares for international travel, but as noted above, emphasises that numerous restrictions remain on direct sales to consumers, to the disadvantage of the latter. We note the comments of the Japanese authorities that airfares require the approval both of Japan and of the other countries involved; and that the aviation authorities implement their flexible operation. We welcome this commitment; but are strongly of the view that greater flexibility would be in the interest of all concerned.

Operating costs, including airport fees

Japanese and European airlines doing business at Japan's major international airports are required to pay very high landing fees, navigation charges, airport terminal rents, airport terminal common user charges, and cargo handling fees that cumulatively make the cost of air transport in Japan the highest in the world. This ultimately has an adverse effect on the Japanese economy, as these costs are eventually passed on to the consumer through higher prices and reduced service. In reply to our comments last year, the Japanese authorities expressed the view that the cost of landing charges; of navigation support service; and of leases on airport building space are unrelated to deregulation. The Japanese authorities also note that IATA and users have been consulted on such charges.

We believe that the Japanese Government can act to ensure that the price levels set by airport authorities no longer function as a disincentive for investment and the provision of air services. The physical circumstances in the Tokyo area are such that natural competition is limited, and a very small number of airports absorb all available flights in the region. Where natural competition is limited, the State has a role in ensuring that there is no abuse of a dominant position, in a manner harmful to the companies and individuals which use the airports in question. The EU notes the recent decision to privatise Narita Airport, and hopes that this will lead to an increase in operating efficiency.

Airport infrastructure and slot allocation

EU operators retain significant concerns as to capacity. We welcome the opening of the second runway at Narita, and we fully understand the environmental and political constraints faced by regulators. Nevertheless, we believe that the current slot

allocation method at Narita should be reviewed, with a view to greater efficiency. At present, slots for the two runways are allocated separately; but they are of unequal length. We would request that slot allocation methodology employed at Narita be reviewed with the goal of improving efficiency, while respecting the increasing level of bilateral economic exchange between Europe and Japan. Such an approach might also ensure greater equality of slot allocation between American and European airlines.

In a more general sense, we would hope that the Japanese authorities can consider whether the allocation of further resources to Kansai is justified; the Kanto region is perceived by EU operators to be neglected as a result.

We understand the comment of the Japanese authorities that "this matter does not fall under the category of ordinary Government regulation"; but would suggest that the Government does have a role to play in ensuring that such matters do not lead to inefficiencies which damage the wider economy. If this problem is not subject to regulation, perhaps it should become so.

Priority reform proposals:

a. In relation to airfares and ticket sales, we would welcome action by the Japanese authorities to remove unnecessary restrictions on ticket sales by operators, for example over the internet.

b. In relation to airport fees, the physical circumstances in the Tokyo area are such that natural competition is limited, and a very small number of airports absorb all available flights in the region. Where natural competition is limited, the State has a role in ensuring that there is no abuse of a dominant position. We believe that the Japanese Government can act to ensure that the price levels set by airport authorities no longer function as a disincentive for investment and the provision of air services.

c. In relation to airport infrastructure and slot allocation, we would request that slot allocation methodology at Narita be reviewed in line with best practices in other OECD countries.

2.5.2 Sea Transport (international shipping)

The main problems faced by the European shipping industry in Japan arise from restrictive working practices on the waterfront. These practices limit competition and operational flexibility and raise the costs of doing business. The "super hub port" strategy of the Ministry of Land, Infrastructure and Transport (MLIT) seeks to reduce costs by as much as 30% at three ports where container handling activities would be concentrated and charges and rents reduced. This welcome policy represents a recognition that costs at Japanese ports – amongst the highest in the world – have been critically undermining their competitiveness via-à-vis other ports in East Asia, to the detriment of domestic and foreign users in Japan. Clearly, removing constraints on competitive conditions for the provision of stevedoring services will be essential if cost-cutting targets are to be met. It should be noted that foreign shipping lines, which carry over 60% of Japan's international containerised trade in and out of the nine main ports, has not been involved in the port selection process.

High port costs can have significant knock-on effects for the rest of the economy. The shipping industry is now recovering from a period of overcapacity. In fact, following a pick-up in global trade, capacity is now in heavy demand. In such a situation,

shipping lines' attempts to maintain the same charges for Japan-based customers as for the rest of Asia are likely to be frustrated as priority will naturally be given to customers in countries with lower-cost ports where margins are higher. This can lead to Japan-based exporters having difficulty getting access to capacity when and where they want it, or to them having to pay a premium to do so.

The situation regarding the Prior Consultation System in Japan remains substantially 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 fortunately been no serious difficulties so far with the Four-Party Agreement now in force, the large discretionary power of the JHTA and the *de facto* restraint this exercises on free competition in harbour service provision, are anomalous. The system continues to inhibit the development of competitive pressures which might push charges down. 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 takes a position of principle 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, basically 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.

Priority reform proposals:

a. ***Ensure that the prior consultation and alternative prior consultation procedures are transparent, equitable and swift.***

b. ***Further review the role of the JHTA in dealing with applications for changes to shipping line operation, with a view to eliminating all vestiges of undue influence on the free play of competition in the provision of harbour transport services in Japan.***

3. Easing the burden of regulation

3.1. Healthcare and cosmetic market regulation

3.1.1. Pharmaceuticals

The European Union acknowledges that the Japanese healthcare system is facing great challenges due to changes in demographics, public finances and issues related to the relative industrial competitiveness of the Japanese pharmaceutical industry. However, it has to be underlined that the availability of affordable, state-of-the-art drugs, irrespective of their origin, will benefit the Japanese population in general.

The Organisation for Pharmaceutical Safety and Research (OPSR) and the Medical Devices Evaluation Centre (PMDEC) were merged in 2004 so as to streamline the consultation and review process. The creation of the Pharmaceutical and Medical Device Agency (PMDA) - an independent administrative agency under the revised Pharmaceutical Affairs Law of July 2002 – is welcomed by the Commission as it is expected to strengthen pharmacovigilance and drug safety.

The EU furthermore welcomes the progress made in the regulatory field, particularly with regard to the reduction of processing and approval times for New Drug Applications (NDA) and notes that NDA approval times have been reduced over the last years. However, according to our knowledge, the target review times as set by the Japanese authorities seem less ambitious than expected. The EU therefore encourages the PMDA to speed up its streamlining of the drug evaluation and approval process in Japan to further reduce the time needed for processing NDA applications.

The EU expects that the new Pharmaceutical Medicine and Devise Agency (PMDA) will increase the quality of drug assessment and provide improved services in line with the increased fees that are requested from pharmaceutical companies.

The EU reiterates that foreign data should be more widely accepted by the Japanese authorities. Concerns still exist with regard to the inconsistent implementation of the ICH E5 Guidelines.[1] Consequently the EU likes to draw the Japanese government's attention to these shortcomings. Discussions on bridging studies between the industry and the Japanese authorities are necessary in order to develop the use of the Guidelines. However, it has to be ensured that these discussions lead to concrete results which help to create a level playing filed for non-Japanese companies.

As regards intellectual property rights the EU strongly urges the Japanese government to allow for an eight-year data protection. The EU is interested in getting first hand information on the state of play on the foreseen legislation concerning data protection.

Priority reform proposals:

a. ***Improve the quality and efficiency of the registration process for new drug applications and ensure that the fees for drug approval are adequate and reflect the services rendered.***

b. ***Ensure consistent and scientifically well-founded implementation of the ICH E5 Guidelines.***

c. ***Provide an appropriate level of IP protection for new innovative drugs, namely an extended data protection period.***

[1] Guidance aimed at facilitating the registration of medicines among ICH regions by recommending a framework for evaluating the impact of ethnical factors upon a medicine's effect.

3.1.2. Medical devices

In view of Japan's rapidly aging population, slow economic growth and rising societal expectations for quality of life, innovative health technology can help deliver higher quality health care to the Japanese people. The EU encourages Japan to proceed further in harmonising its regulatory requirements with those of its major trading partners. Further, the EU urges the government of Japan to embrace innovations in health care technologies that allow health care resources to be used more effectively and that will represent an investment in the quality of life and productivity of Japanese patients. Regulatory reform applied to health technologies in Japan should be further promoted to enable beneficial technology 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 GHTF, and the adoption of its recommendations, are strongly encouraged.

The EU welcomes the replies received from the Japanese government but would like to reiterate the importance of ensuring that pricing and reimbursement policies support the innovation process and are aimed at stimulating continued investment in medical devices industry by both domestic 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 time to market, which is now one to two years, or even longer for a new product. 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 cost effectiveness information based on foreign clinical data. Furthermore, linking decisions on domestic pricing and reimbursement levels to those in foreign countries appears discriminatory and is unfair since it ignores the high cost of doing business in Japan, including differences in medical, reimbursement, distribution, and business practices. This can lead to the perverse situation whereby companies may choose not to market their some of their most innovative products in Japan.

Priority reform proposals:

a. ***Further implement regulatory reform by streamlining and improving the transparency of product approval, taking into account world-wide data, and applying sound science and risk benefit assessment, in line with GHTF Guidance documents.***

b. ***Recommend in the field of medical devices the early adoption and use of international standards (ISO and IEC standards) without additional national requirements. This policy is consistent with the recommendations of the Global Harmonisation Task Force (GHTF) on the role of standards.***

c. ***Reduce time to market for new health technologies by handling regulatory approval and reimbursement approval in parallel, and further improve access for new products by accepting cost-effectiveness information based on foreign clinical data.***

3.1.3. Blood plasma

A stable and sufficient supply of blood plasma is essential for any medical care system. Since large volumes of plasma are required to manufacture plasma-derived medicinal products international trade in plasma products helps to ensure a sufficient

supply and minimises risks which may arise due to single-sourcing. By way of introduction, the EU would like to point out that European products are safe and manufactured according to the highest international standards.

Legislation applicable to blood products in Japan has been the subject of extensive revision. In the 2002 ordinary session of the Diet, the Blood Collection and Donation Arrangement Control Law ("the Blood Law") and the Pharmaceutical Affairs Law were amended.

One element is of particular concerns to the EU:

The Japanese government's implementation of recent amendments to Japan's "Blood Law" contains, among other things, a supply and demand plan under which companies are obliged to provide specific information about future supply, in order to allow this information to be compared with estimated demand. The objective of this plan is to promote blood self-sufficiency. Furthermore it creates a regime under which the government reserves the right to take action to restrict the importation of plasma-derived medicinal products whenever it determines that these are reducing demand for domestically sourced blood products. Non-compliance with the plan, i.e. increased imports, may lead to fines or even the shut down of business operations in Japan.

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.)"

In addition the Japanese government seems to implement a national medical insurance program, under which domestically-sourced blood products receive higher list prices and insurance reimbursement rates than imported products. Hence imported blood products are treated in a less favourable way than domestic products.

Both points raise serious concerns as they are inconsistent with Japan's GATT obligations and may constitute an unfairly restriction of imports into Japan and/or non-national treatment with regard to the pricing and reimbursement of plama/blood-products.

Priority reform proposal:

The EU requests Japan to reconsider the presumption in favour of domestic blood plasma on which the supply/demand provisions of the new Blood Law are based, and to formulate provisions which do not inherently discriminate against importers.

Consequently the EU urges Japan to lift any implicit and/or explicit provisions and practices which unfairly favour domestic plasma-derived products and to give full explanations concerning the pricing and reimbursement scheme in force.

3.1.4. Cosmetics

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

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

The EU would welcome Japan's intention to consult further with foreign countries in order to harmonise regulatory approaches and/or requirements in the field of cosmetics.

The "quasi-drug" category used by Japan remains a concern for EU economic operators. A broad range of products ranging from deodorants, hair dyes, hair growers and depilatories, medicated cosmetics (notably whitening agents) and medicated toothpaste to sanitary napkins and over-the-counter health drinks is still subject to this special legislation while most of the products covered are considered "normal" cosmetics in other countries. Despite some changes which have limited the scope of products covered by this regulation concerns persist. As the criteria for classification as a quasi-drug are often not clear and new ingredients to be included in the quasi-drug category (including some ingredients already accepted as ingredients in "normal" cosmetics) face nearly insurmountable obstacles a fundamental reform of this category seems to be worth considering. Bringing the Japanese product categories in line with well established international practices would be considered a major step towards the full implementation of the Deregulation Programme of March 1999.

In view of the ongoing process of progressively replacing animal testing by scientifically-validated alternative methods, the EU would welcome Japan's official confirmation that it will recognise safety data generated from non-animal alternative testing methods in accordance with the OECD guidelines. Mutual acceptance of testing methods would be considered a major benefit of international harmonisation. However, to date the EU is not aware that Japan has changed its stance and modified its insistence on data derived from animal tests

Priority reform proposals:

a. ***The EU requests that common products such as deodorants, hair dyes, permanent wave products, depilatories, etc. should be regulated as cosmetics. In***

the meantime, the EU requests Japan to ensure full transparency with regard to already approved active ingredients in quasi-drug products (as already done for hair dyes and perms). The full publication of a nomenclature list, specifications, and doses would be seen as a first step to allow for easier registration of new quasi-drug products.

b. The EU restates its offer to Japan to consult with EU regulatory agencies with the aim of internationally harmonising positive and negative lists, and establishing mutually recognised testing and acceptance criteria for adding new ingredients to these lists.

c. The EU requests Japan to provide information concerning the conditions for acceptance of non-animal testing data on cosmetic products, including concrete evidence of acceptance of this data.

3.2 Distribution

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

3.2.1 Retail licences for large stores

The EU welcomed the entry into force on 1 June 2000 of the new Large Scale Retail Store Location Law (*dai ten ricchi ho*, LSRSLL). Although the overall transparency of the notification procedures has increased, the implementation of the law has remained unclear and needs further clarification. There is no clear rule on the timing of the submission of a notification to local governments, nor coordination between the LSRSS and the Building Permit procedure. Some companies start construction simultaneously as they submit notifications to the local authorities in order to shorten their project lead-time, at their own risk that subsequent changes may be required to their plans. Foreign retailers, which have less experience and networks with local communities, are often left in a disadvantageous position. Moreover, some local governments have imposed new local rules on applicants that negate the original purpose of the LSRSLL, making the procedure to open new large-scale stores more complicated, not less. The EU considers that monitoring the implementation of the law remains crucial in order to avoid the risk of excessive regulation at local level.

Although the EU welcomes the establishment of a contact point in METI and its local offices in order to help operate the LSRSLL smoothly, in the light of the above the EU maintains its proposals in this sector. The EU notes that domestic bodies such as Keidanren and the Japan Chainstore Association have also asked that local authorities to apply the LSRSLL in a fair and consistent manner, and that the administrative burden placed on applicants seeking to open new stores be reduced in line with the original intent of the Law. The EU understands that METI is planning to review its guidelines in March 2005 and would be interested in more detailed information concerning this revision.

Priority reform proposal:

The EU suggests to clarify the guidelines on the implementation of the Large Scale

Retail Store Location Law and monitor implementation by local authorities of procedures for handling applications under the LSRSLL to allow consistent and fair application of the guidelines throughout Japan.

3.2.2 Alcohol licensing

Alcohol sales licensing has been progressively liberalized, in January 2001 and September 2003. The restrictions based on distance and population have been abolished. However, the "Temporary Adjustment Law for the improvement of Business Conditions of Liquor Retailers" enacted in August 2003 (Law No. 34) effectively wipes out the beneficial effects of liberalisation. According to the new rules, the director of the local tax office can designate his jurisdiction as an "Urgent Adjustment Area" (*kinkyu chosei chiiki*) for the duration of one year if supply exceeds demand and if sales volumes for FY 2003 have dropped by more than 10% of the average of the three previous years for more than 50% of the incumbent retailers. As of September 2004, the number of areas designated as "Urgent Adjustment Area" increased from 922 in the previous year to 1,274 (an increase of 38.2%). Instead of slowly phasing these areas out, the ratio of these areas to the total number nationwide has now actually risen from 27.3% to 37.7%, thereby worsening the situation considerably.

The status of these "Urgent Adjustment Areas" is being reviewed annually until the expiry of the rules, currently scheduled for 31 August 2005. The EU would appreciate a confirmation that the Law No. 34 regarding the "Urgent Adjustment Areas" will effectively be allowed to expire as scheduled. The EU is concerned that, if these rules were to be prolonged beyond FY 2005, it would further affect foreign investment as it would considerably hinder predictable planning.

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

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

Priority reform proposals:

a. ***The "urgent adjustment areas"* (kinkyu chosei chiiki) *should be abolished and not be renewed after expiry of the respective law in August 2005.***
b. ***Companies should be able to apply for a liquor license under the new licensing scheme without having to wait for their large-scale store license to expire.***

c. Liberalisation of the retail liquor system should be extended to wholesale licensing as well.

3.3. Promoting international standards

3.3.1. Building standards – formaldehyde emission regulations for construction products

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

Testing and performance evaluation are required under JAS or JIS rules, or via the Ministerial Approval scheme of the Building Standards Law (BSL). The majority of wood-based products exported by the EU are covered by either the Ministerial Approval or JAS schemes. However, no testing organisations within EU have been approved to carry out testing and performance evaluation. EU exports are thus subject to considerable costs and delays because of capacity bottlenecks amongst the Japanese performance evaluation bodies and testing institutes approved by MLIT. Volumes of trade which constitute up to 13% of the export profile of certain EU Member States to Japan, have thus been put in jeopardy.

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

- MLIT is making efforts to speed up on the Ministerial approval procedure as long as it does not harm fairness with other applicants and the EU would be grateful for information about progress made so far and how many EU bodies have applied and which one have been approved.
- In case there are any problems regarding the co-operation of EU testing organisations, the EU side would appreciate being kept informed.
- The EU understands that certain differences of requirements between Japanese regulations and the CE marking system do exist and would appreciate further information on these differences and how they could be overcome.
- The EU appreciates the information and clarification given regarding the possibilities for competent bodies in EU Member States to apply for designation to the Minister. The EU would be grateful for confirmation that there are no additional barriers for these bodies to overcome before they can service their customers within the EU.

Priority reform proposals:

a. Continue the efforts made to accelerate the process of Ministerial Approval for products which have initiated the approval process but which have not yet been approved;

b. Continue to make efforts to promote and facilitate subcontracting by Japanese performance evaluation bodies of the testing function under the Ministerial Approval scheme to EU testing institutes;

c. Confirm the EU understanding that competent European bodies are entitled to carry out testing and performance evaluation resulting in a certificate which will be recognised by Japanese authorities;

d. Explain the differences encountered between the CE marking system and corresponding Japanese regulation in order to explore possibilities for acceptance of CE marked products.

3.3.2. Motor vehicles - Adoption of UN Regulations

The EU believes that the international harmonisation of automobile regulations is in the fundamental interest of all producing nations, especially as the auto industry is in every aspect a truly global industry. The EU has noted with great satisfaction that several UN regulations that the EU had identified as a priority for adoption under the revised 1958 UN Agreement, have in the meantime been adopted or are due to be adopted within fiscal year 2004 (e.g. R14, R37 and R113).

Having said that, the EU notices that a number of UN regulations which it had identified as priority items, are according to its information not scheduled for consideration up to 2010 (e.g. R4, R90, R97 and R103).

The EU, therefore, maintains its request that the Japanese side should sign up quickly to a significant number of the annexed regulations. In this respect, the EU is of the firm opinion that the current adoption rate of 5 to 6 regulations per year should be speeded up.

The EU continues to believe that 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 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 indicated in its answer to last year's EU priority proposal that it will accede to UN regulation 104 on retro-reflective markings for heavy and long vehicles. The EU would be interested to know for when the signing up to this UN regulation is scheduled.

Priority reform proposal:

The EU has a long standing request for Japan to speed up its adoption of UN regulations. The EU requests that (i) beyond 2004 the number of regulations adopted per year could be accelerated considerably, and (ii) Japan should in this work incorporate the following priority list of UN requirements: Japan should accede to all remaining lighting regulations; viz UN R4, R53, R74, R87, R98, R99 and R112 . As a logical consequence of making safety a priority, the EU also hopes that Japan will give priority to the following package: UN R13, R16, R43, R44, and R46. Other important regulations for adoption would be UN R51, R59, R90, R97 and R103. Finally, the EU hopes that UN R14, R37 and R113 will be adopted as initially scheduled during fiscal year 2004.

3.3.3 Tank containers

Responsibility for various categories of dangerous goods remains divided between (i) Fire and Disaster Management Agency (FDMA) of the Ministry of Internal Affairs and Communications (MIC) – flammable liquids, (ii) Ministry of Economy, Trade and Industry (METI) – high pressure gases, and (iii) Ministry for Health, Labour and Welfare (MHLW) – toxic materials.

Significant improvements have been made in this field. Costly additional inspections of newly imported tank containers were abolished on 30 March 2002, and have been replaced with a notification-only system. The EU appreciates that FDMA responded to complaints from the EU and other parties about fire stations at some ports that still undertake unnecessary inspections after that date. All ports have now moved to the notification-only system. This is a step towards international standards, given that tank containers entering Japan have been previously inspected and certified in line with the UN Recommendations on the Transport of Dangerous Goods (IMDG code) and there is no need for a national or local administration to query the approvals already granted.

However, after more than two years since the new system has come into effect, the European Commission is told by the industry that the fire stations around Japan still ask that the documents in question be presented in person and stamped by a fire officer, despite the fact that the relevant regulations allow notification to be done by, for example, fax or electronic means. In practice, the trucking company or customs agent charges the owner or lessee of the container between 5000 and 20,000 Yen (between 37 and 149 euro), and on average 15,000 Yen (112 euro) per notification. There are thousands of such notifications each year at ports throughout Japan, constituting a considerable cost burden to the industry. The FDMA promised to instruct the fire stations to implement the system according to the regulation, but some fire stations have still not yet implemented the regulation. This could be avoided if FDMA ensured that a real notification-only system be instituted. As it functions at present, the notification system adds paperwork and cost while in no way increasing the safety of tank containers which in any case already comply with the relevant international standards.

Priority reform proposals:

a. ***In the short term, the EU requests FDMA to ensure that fire stations at Japan's ports implement the letter and spirit of the revised regulations, i.e. a proper notification-only system which does not require physical presentation of the documentation but only fax or e-mail (with reply notifying receipt, if necessary);***

b. ***Abolish the notification system in the medium term. If necessary, random checks can be used to determine whether tank containers are carrying the correct IMDG-compliant documentation. No additional requirements (e.g. notification) should be necessary above and beyond compliance with the IMDG code.***

3.3.4. Packages for foodstuffs

The Japanese regulation applicable to packages for food is the Food Sanitation Law, announcement from the Ministry of Health, Labour and Welfare n° 370, issued on 28 December 1959. This regulation sets mandatory product and testing requirements for packages which may create an unnecessary obstacle to trade. While most Japanese

packages for food are retort pouches and therefore comply with the rules concerning retort pouches, European Union companies have chosen a somewhat different approach not resembling pouches. Instead they have invented a product similar to a milk carton equally suitable for serving as a container for food or beverages. This means that some of the requirements and limits for retort pouches, mainly testing requirements, cannot be applied to this new kind of package.

The problem faced by European Union industry could be solved by splitting different pouch materials into different categories depending on material used. This would allow to take advantage of the benefits of the different materials as each of the materials used for packaging, be it metal, plastic, glass or carton as in a milk carton have different benefits and advantages.

Priority reform proposal:

The EU urges the Japanese government to modernize 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 result. Therefore, testing requirements should be modified according to the state of the art of technology in this field. Innovation should be taken into account by Japanese authorities and allow for new products to be placed in the market.

3.4. Food safety and agricultural products

3.4.1. 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.

While food safety must remain a priority, the manner in which Japan's MHLW has responded to recent scandals is a matter of serious concern to the European Union. As has been publicly stated by the Ministry, a large number of food recalls ordered recently by MHLW have been made despite there being no human health concerns at stake. These recalls have involved products containing flavourings and additives manufactured in Japan (in some cases for over 30 years), as well as products in common use around the world.

The European Union follows closely the work of the CODEX Alimentarius on determination of the safety of ingredients and additives, according to internationally accepted scientific methods. Japan should also implement international standards and bring its list of approved food additives into coherence with the CODEX Alimentarius, an organization to which Japan adheres and provides support.

The Government of Japan (GOJ) has decided to give priority to evaluation for the authorization of 46 food additives, including 38 priority substances proposed by the EU. Although these substances were evaluated by the JECFA, and are distributed 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. Currently, 8 food additives and 6 flavouring agents for which full documentation has become available are under risk evaluation at the Japan Food Safety Commission.

The EU proposes that all these substances should be approved as one package in place of the current practice, which is considered redundant and inefficient, as it will likely take around 10 years for the Japan Food Safety Commission to work through a priority list of 46 substances, which have already been thoroughly evaluated elsewhere. It appears unlikely that the isolated review of GOJ will reveal any formerly unknown information. On the contrary, issues of data ownership sometimes stand in the way of making all studies evaluated elsewhere also available to Japanese authorities.

Japan should consider a mutual recognition of authorisations granted for food additives in the EU. This step would be in the spirit of the EU-Japan Investment Framework. 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

Priority reform proposal:

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

More specifically, the EU invites the Japanese government to speed up the evaluation and authorisation process for 46 priority substances, including the 38 proposed by the EU.

3.4.2. Import of cut flowers, pot plants in approved growing media, fruit, vegetables - Japanese list of non-quarantine organisms

Japan's Plant Quarantine Law was partially revised and passed by the Diet in June 1996, but so far this revised law has had a limited effect on imports of plant products because in practice it does not make a scientifically justifiable, practical distinction between harmful ("quarantine") and non-harmful ("non-quarantine") organisms.

Japan's list of non-quarantine organisms is incomplete and many common organisms which are present both in Europe and Japan, such as aphids and mites, are not included on this list. Any plant products which have such non-harmful organisms on them are treated by Japan in the same way as if they were infested by harmful organisms and must be fumigated or rejected for import. The regulations are not in line with international standards and norms. In line with the Government of Japan's commitment set out in the deregulation package of 31 March 1998, regulations should be modified to conform to the principles of the WTO SPS Agreement.

In February 1999 the European Commission requested the addition of 9 priority organisms to the Japanese list of non-quarantine organisms, and this was repeated in a

letter dated 28 July from then Director-General Legras to then Vice-Minister Kumazawa. In his reply of 24 January 2000, Mr Kumazawa refused to add the 9 organisms to the non-quarantine list, but indicated that Japan is studying the possibility of introducing tolerance levels and alternative methods of disinfection. The results of this study, which were promised in early 2001, are not yet available to the European Commission.

Pursuant to a report of a Consultative Group on Plant Quarantine, which was released on May 21, 2004, the GOJ has initiated a new Pest Risk Analysis including pests that EU has requested to designate as non-quarantine pest. The GOJ made its position clear at 30th SPS committee that it will take available measures based on the result of the new Pest Risk Analysis; for this purpose, as an initial step, the GOJ will start necessary procedures for the WTO/SPS notification at around December 2004.

The European Commission reacted to this report and conveyed its concern that the report of the Consultative Group on Plant Quarantine fails to take into account fundamental principles and articles of the IPPC and ISPM.

The European Commission notes that the report suggests that a PRA should be completed before measures are put into place. This would imply that only for those quarantine pests, for which Japan has completed a PRA, measures can be maintained. At the very least, Japan should ensure as a matter of priority technical justification for all those pests which are regulated at present, but for which no PRA or similar evaluation has been carried out so far.

The European Commission further notes that the approach proposed within the report on the application of ISPM 15, i.e. the international standard for wood packaging material is unacceptable and not in line with the requirements of the SPS Agreement. Japan is a member of the IPPC, presumably attended all the meetings where ISPN 15 was discussed and should apply the recommended measures without further delay or modification.

Priority reform proposal:

The EU requests that the Japanese list of non-quarantine organisms be extended to include all non-harmful organisms found in fruit and vegetables, cut flowers, pot plants in approved growing media. As a first step the 9 organisms specifically requested by the EU should be added to the list. In parallel, tolerance levels should be established for quality viruses which are not on the non-quarantine list. These tolerance levels should benefit all EU Member States.

3.4.3. "Regionalisation" – recognition of the EU's single market as regards animal and plant products

Japan has not yet recognised that a single market for animal and plant products exists in the EU and has not yet implemented the provisions of the Sanitary and Phytosanitary Standards (SPS) agreement of the World Trade Organisation (WTO) on regionalisation with respect to this single market. Each EU Member State must therefore negotiate bilaterally and pass through lengthy approval procedures for each new variety or type of animal or plant product which it wishes to export to Japan.

The EU applies the principle of regionalisation internally within its external borders in accordance with international guidelines as explained in G/SPS/GEN/101. Japan can therefore have confidence in the legal Decisions taken at a European level with

respect to regionalisation and consider the disease/pest free areas recognised by these Decisions when applying import measures on products from EU Member States.

To illustrate the underlying exchange of information and regulatory scrutiny of its regionalisation Decisions, the European Commission submitted a case study using a historical outbreak of Classical Swine Fewer as an example. The study was submitted by the EU in February 2004 but still no comments have been received from Japan. A proposal to conduct a similar case study with plant products was not taken up by Japan so far.

The GOJ so far has responded that it cannot accept the EU as a single quarantine region, because the effect of quarantine measures taken by a member state cannot automatically apply to another member state. If the GOJ were forced to view the EU as a single quarantine region under the current circumstances, this would mean that it cannot help but apply the quarantine measures that are taken by a country with the lowest level of standard of quarantine system in the EU.

However, the European Commission respectfully submits that it has never requested Japan to "view the EU as a single quarantine region". What was asked for is that the Japanese competent authority should study the Community rules for the control of notifiable diseases[2], and evaluate, on the basis of one or more case studies submitted by the Commission, whether it cannot generally recognise the EU regionalisation Decisions which are based on these rules. This would allow trade to continue from disease-free areas without disruption or delays and without any compromise on the level of sanitary protection.

The EU would be pleased to enter into a technical dialogue with Japan on regionalisation and other, wider questions related to animal disease control with a view to extent the bilateral collaboration in this area. The case study submitted on Classical Swine Fever is hoped to provide a starting point for such a dialogue and comments from Japan are awaited with much interest.

Priority reform proposal:

The EU requests that Japan should have confidence in the legal Decisions taken at a European level with respect to regionalisation in the case of an outbreak of a notifiable disease in the Community. Any disease/pest free area recognised in such an EU Decision went through scrutiny of all 25 Member States. Decisions in this area should also be recognised by the GOJ when applying import measures on products from the EU. At least the GOJ and the Commission should establish a pragmatic process to achieve such recognition within the shortest delays.

3.4.4. Regulatory procedures for acceptance of varieties of fresh fruit and vegetables

The duration of SPS approval in Japan is far too long – it has taken up to 20 years for the marketing approval of some citrus fruits. Although progress has been made and import restrictions were recently lifted for Spanish Salustiana and Clementina oranges and Belgian tomatoes, the general problem of very slow processing remains. Notably for Italian fruits and vegetables the GOJ has planned for a public hearing to be held, but the EU notes with regret that no such hearing has yet taken place.

[2] Generally a framework legislation, contingency plans, reference laboratories, and other elements. Any regionalisation measure of the EU is based on detailed information submitted by the affected Member State and depends from the agreement of all other Member States with qualified majority.

Following outbreaks of Mediterranean fruit flies, tobacco blue mould and fireblight are reported in Belgium, Spain, FranceItaly, Hungary and Greece. Japan has prohibited the import of certain host plants of these harmful insects from these countries. The import bans were lifted in several cases. In the case of oranges from Italy, plant quarantine authorities of both Japan and Italy are examining disinfestations techniques against Mediterranean fruit flies.

With respect to Italian kiwi, grapes, pears and apples, the EU is expecting GOJ to review information about quarantine measures to prevent the invasion of harmful insects. The GOJ states it is awaiting information from Italy.

On French apples the GOJ states it is also awaiting pertinent information on quarantine measures from France.

The EU requests to be kept informed on the further progress with respect to the Italian application for oranges following the inspection of February 2004 and on Kiwi fruit; the EU is in particular interested in the results of a meeting on this subject in June 2004.

Priority reform proposal:

The EU requests Japan to extend its list of non-quarantine organisms to include all non-harmful organisms, found in fruit and vegetables, cut flowers and pot plants, as identified by IPPC. More in detail, the EU requests Japan to process import requests without undue delay especially with respect to several outstanding current applications (i.e. Italian fruits and vegetables - notably the orange variety Tarocco, Hungarian and Greece fruits and vegetables) and other pending cases. SPS approvals should be processed more quickly and without undue delay.