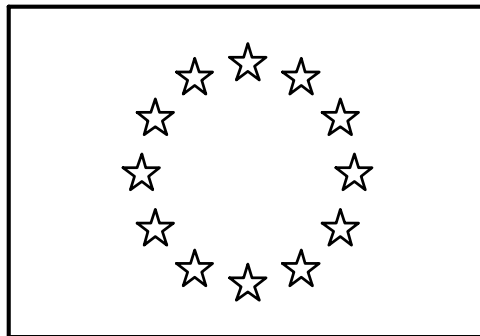


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EU Proposals
for Regulatory Reform in Japan

Final version



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Table of Contents

Introduction	4
1. Investment	6
1.1 <i>Corporate restructuring and related measures: the case of mergers and acquisitions (M&A)</i>	6
1.2 <i>Legality of branches: quasi-foreign companies</i>	8
1.3 <i>Human Resources</i>	10
1.4 <i>Transparency</i>	13
2. Government Procurement	16
3. Information and Communications Technology (ICT)	23
3.1 <i>Strengthening the competitive safeguards to guarantee transparent, non-discrimination and cost oriented access to bottleneck facilities and interconnection.</i>	23
3.2 <i>Universal Service Financing</i>	25
3.3 <i>Global harmonization of spectrum for IMT-Advanced (systems beyond IMT-2000)</i>	28
3.4 <i>Market access for telecom terminal equipment</i>	29
4. Financial services	31
4.1 <i>Banking and investment services</i>	31
4.2 <i>Insurance</i>	34
4.3 <i>Auditing</i>	37
4.4 <i>Accounting</i>	39
5. Privatisation of Japan Post	41
6. Transport	45
6.1 <i>Air transport</i>	45
6.2 <i>Sea transport (International Shipping)</i>	47
7. Healthcare and Cosmetics	49
7.1 <i>Pharmaceuticals & Vaccines</i>	49
7.2 <i>Medical devices</i>	51

7.3	<i>Blood plasma</i>	55
7.4	<i>Cosmetics</i>	56
8	Food safety and agricultural products	57
8.1	<i>Food Additives and Flavourings</i>	57
8.2	<i>Imports of Bovine and Ovine Products (Especially Beef)</i>	59
8.3	<i>Organic Food Certification</i>	60
8.4	<i>Phyosanitary Regulations</i>	62
8.5	<i>Breeder's rights</i>	64
8.6	<i>Regionalisation</i>	65
8.7	<i>Import Controls - Appeal procedures</i>	67
8.8	<i>Import controls</i>	68
8.9	<i>Casings</i>	69
9.	Wood standards	70
10.	Animal health products	73

Introduction

The European Union appreciates the Government of Japan's commitment to the Regulatory Reform Dialogue over the past 13 years.

At the 16th EU-Japan Summit in Berlin in June 2007, Japan and EU leaders recognised the "well-functioning and the progress achieved in a number of bilateral dialogues under overall supervision of the High-Level Consultations, in particular the Regulatory Reform Dialogue". The EU particularly appreciates the openness and transparency of the dialogue which has taken place with the GoJ on the issues related to triangular mergers.

The EU firmly believes that continued structural reforms remain a necessity, both for Japan and for the EU, in order to boost economic growth against a backdrop of intensifying international competition as well as societal change (e.g. ageing populations). On the EU side, these challenges are being tackled in particular through the renewed Lisbon Strategy for Growth and Jobs. The EU's Better Regulation policy is also important in this regard. On the Japanese side, the EU warmly welcomes the clear commitment by Prime Minister Fukuda in his October speech to the Diet to pursuing further reform efforts and his recognition of the importance in this regard of promoting domestic and foreign investment.

The EU and Japan clearly face a number of common challenges in relation to regulatory policy. In this, as in many other areas, they are pursuing a number of common objectives: e.g. a high level of safety and consumer protection; a commitment to safeguarding the environment; a desire to foster innovation as a driver of economic growth.

Against this background, the EU is convinced that the Regulatory Reform Dialogue is more relevant and useful than ever. Developed economies like Japan and the EU have a common interest in sharing experience and advice on reform-related issues.

Given the value of the RRD, the EU and Japan have a joint responsibility to ensure that this process remains adequate in light of the growing scope and complexity of the regulatory issues at stake. If this proves necessary, working methods should be modernised. The European Union is looking forward to working with the GoJ over the next few months to review the RRD in order to see whether changes would be beneficial to further enhance its contribution to the EU-Japan bilateral cooperation.

The EU hopes that the proposals following below will be taken into consideration by the Council for the Promotion of Regulatory Reform (CPRR) in elaborating its recommendations for 2008 and by the Government of Japan in continuing the path of necessary reform measures.

Changes in this document compared to 2006

As in the past, this paper reflects a number of developments over the past 12 months, as reported in the Japanese final replies to the EU 2006 proposals as well as in bilateral contacts, or observed through open-access sources.

Thus, a small number of issues can be deleted from the RRD agenda, while the focus of several other items needs to be modified, and yet other new issues need to be added.

Concerning deletions, the EU has omitted the long-standing issue of food packaging on the strength of the expectation that the amendment to the relevant law will be adopted possibly even before the date of the RRD meeting. The issue of motor vehicle standards has also been omitted as its main objective – acceleration of the Japanese take-over of UN-ECE Recommendations – can be pursued in a more targeted way in the UN-ECE itself. It should be noted, however, that the EU clearly keeps the option of raising these issues again in the RRD if the expected positive developments were not to take place.

The broad range of proposals following below reflects the continuing large extent of EU concerns and interests in regulatory matters in Japan. On many of the issues, the progress observed since the last RRD round was slow and did not address all issues raised. However, the main topic on which the focus has been changed is chapter 1 – Investment where the measures adopted by Japan on 1 May 2007 have considerably improved the situation, though leaving other aspects to be raised.

New issues are raised in chapters 1.3 where a problem related to obtaining driver licences has been added. Also, chapter 4.4 - Accounting standards has been added as well as chapter 3-4 on market access for telecom terminal equipment. Chapters 8.7 and 8.8 on Import controls and chapter 8.9 – Casings also concern issues which have surfaced more recently.

Finally, the presentation of issues has been streamlined, notably with a view to providing short essential information (“Highlights”) and to underline the continuity in the EU approach (“case history”). Moreover, coherence in the EU’s overall efforts is underlined, where applicable, by the newly introduced references to other dialogues where the same issues are being addressed.

1. Investment

1.1 Corporate restructuring and related measures: the case of mergers and acquisitions (M&A)

Highlights:

The EU welcomes the good cooperation and the important steps taken by the Government of Japan (GoJ) to facilitate mergers and acquisitions in order to increase inward investment. Therefore, this year, the EU does not see a particular need to come up with new proposals. However, it would like to focus a number of selected issues to keep the RRD involved and to show the EU's commitment and interests: the EU would like to encourage the GoJ to make sure that the issues of tax deferral for triangular mergers and of broadened notification requirements in sensitive sectors will not lead to - nor be perceived as - barriers to foreign investors, going beyond the GoJ's intentions.

Case history: first raised in 2005, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not fully remove EU concerns.

Triangular mergers

The EU welcomes the entry into force of the new Corporate Law this May allowing cross-border share-for-share mergers, under the 'triangular merger' formula (foreign parent companies using their shares through a 100% Japanese subsidiary, when merging with or acquiring another Japanese company) on an equal footing with domestic mergers. This is in line with the EU request expressed in the EU-Japan Regulatory Reform Dialogue (RRD) since 2005. The EU appreciated very much the good cooperation and consultation on this issue with the GoJ. The EU will closely watch developments in the M&A. It reiterates its support to the GoJ's continued commitment to increase its inward FDI to 5% of GDP by 2011.

Tax-deferral for triangular mergers

The EU welcomes the measures adopted by the GoJ which extend the tax-deferral rules on capital gains available for domestic corporate reorganisations between Japanese companies to cross-border triangular mergers, thereby ensuring a viable and attractive M&A market for foreign operations in Japan. However, this tax-deferral is not extended to so-called 'paper companies'¹. As the subsidiary used in the transaction is often set up for the sole purpose of being a vehicle in this merger it could easily be classified as a 'paper company' and thus not enjoy tax-deferral. To create a clear legal situation, a Ministerial

¹ The term 'paper company' is used here in the sense given to it in the relevant discussions in Japan: it does not imply any judgement on the legality of such companies.

Order of the Ministry of Finance set out the criteria for such subsidiary to fulfil in order not to be classified as a 'paper company'. It is not clear whether this creates the desired legal certainty. The EU will therefore continue following the developments on triangular mergers closely to see whether the system does create an unnecessary burden on European companies wanting to invest in Japan through M&A. It should be noted that Japanese companies wishing to invest in the EU are not subject to any equivalent restrictions as regards the use of special purpose vehicles or 'paper companies'.

Mergers and acquisitions in sensitive sectors

The GoJ expanded the scope of sectors which fall under the notification requirement (according to the Foreign Exchange and Trade Control Law and the amended Ministerial Order) to include defence technology related sectors this September. The EU appreciated the open consultations with and the explanations of the GoJ on this issue during the drafting phase of the amendment to the Ministerial Order. We trust that the expansion of the scope will not create additional unnecessary burdens for investing in Japan. The EU understands from a perspective of national security that those measures need to be taken, but it is at the same time closely watching the developments in this field to ensure that daily business transactions of European companies are not unnecessarily hampered.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To ensure that tax-deferral for triangular mergers will not be applied in such a way as to become a barrier to foreign investment and that legal certainty can be achieved in this field;**
- b) To clarify the new broadened notification requirements on foreign investment concerned by mergers and acquisitions in sensitive sectors in Japan and to ensure that it does not have more than necessary restrictive effects on investment.**

1.2 Legality of branches: quasi-foreign companies

Highlights:

The EU would like to reiterate its concern regarding the unnecessary complications for foreign companies, in particular for those in the financial services sector, created by Article 821 of the new Corporate Law. While the GoJ has made considerable efforts to clarify that Article 821 does not intend to target 'legitimate' foreign business operations, the prevailing sense in the foreign business community is that the current situation continues to be unsatisfactory from the point of view of legal certainty, and has generated considerable costs, confusion and concern. Many companies affected feel that the GoJ undertook this step because it prefers companies to incorporate.

Case history: first raised in 2005, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove EU concerns.

Article 821

Article 821 of the new Corporate Law has profound repercussions for many European companies, as it puts into doubt the legality of their business operations in Japan: the new Corporate Law provides that foreign companies having a main office in Japan or whose primary business purpose is to conduct business in Japan (so-called "*quasi-foreign companies*") are not allowed to engage in transactions on a continuing basis in Japan (Art. 821 para 1). Persons acting in violation of this rule are liable to contractual countermeasures (Art. 821 para 2), with the possibility of sanctions (Art. 979 para 2).

While the Ministry of Justice (MoJ) has made interpretative statements (*tōben*) on the record during the Diet hearings on the scope of application of Article 821, and the Diet has taken the rare step of issuing a Parliamentary Statement (*futai ketsugi*) together with the adoption of the bill, a literal reading of Article 821 means that those business entities engaging in transactions on a continuous basis risk to be prosecuted.

Even though the GoJ assured us in the replies to 2006 year's proposals that courts will not interpret this article literally and that judges take into account relevant provisions and the discussions held in the legislation process, many European headquarters continue to be concerned about the legal risks entailed. Courts are bound only by the letter of the law and not by statements made during the legislative process. As this is particularly strongly felt by European headquarters, chief representatives of branches in Japan are obliged to remedy the situation.

This means that companies which are not prepared to accept this legal risk have to convert to domestic status. A number of companies (mostly big ones) have thus incorporated their business operations in Japan. Many others (the smaller ones) are more reluctant to take such a step since conversion is

extremely costly and time-consuming for a number of reasons. Capital gains tax and consumption tax would be levied at the time of transfer of assets, and all contracts with suppliers and customers would need to be re-negotiated. The potential tax burdens in case of a transfer of franchise business constitutes the most significant risk factor for some firms, in addition to costs for accountants, legal counsel, renewal of contracts, systems, publications and stationary, registration fees for paid-in capital, plus immeasurable labour costs.

Companies in the financial sector are of course particularly affected: as a consequence of the legal separation of banking and securities operations in Japan (Article 65 of the Securities and Exchange Law), many European companies decided to establish themselves in third countries (as so-called Special Purpose Companies, or SPC) and operate through branch offices in Japan. But the EU has been informed that European trading companies, pharmaceutical companies, law firms, as well as consultancies and project management firms were also affected. Despite the fact that the scope of the article itself might be limited, as written in the Japanese replies to EU 2006 RRD proposals, it does affect a sufficient number of European companies.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To finally clarify and minimise the economic impact of the implementation of Article 821 of the new Corporate Law on foreign companies, as GoJ expressed interest in continuously watching out this impact (see 1-2-a of the final Japanese reply to the 2006 EU request). For the EU side, companies operating in the financial services sector, but also trading companies, law firms, consultancies and project management firms, are affected;**
- b) To amend Article 821 of the new Corporate Law in order to create legal certainty. The EU would appreciate an early indication of a commitment by the GoJ towards that end, as well as an assurance that the European business community in Japan will be given an appropriate opportunity to participate in the revision process;**
- c) To make incorporation easier, in case the GoJ is of the opinion that it is better to incorporate for foreign companies. This would be facilitated by allowing foreign companies to merge into a Japanese company.**

1.3 Human Resources

Highlights:

The importance of human resources-related issues and their potential impact on investment is recognised by the Japanese government and the EU. Pursuing regulatory reform in this field remains an important objective.

Good progress has been accomplished on pension schemes through the conclusion of bilateral agreements with some EU Member States. However, concerns remain on this issue for citizens from Member States not yet covered by a bilateral agreement. Furthermore, in addition to the recurrent concerns related to re-entry permit, and admission of personnel with specific skills, the EU would like to raise new issues related to sponsorship of domestic staff and driving licences.

Case history: first raised in 2002, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

General comments

National laws and regulations relating to human resources may play a role in investment and location decisions of companies. Both Japan and the EU, when assessing the cost-effectiveness of measures relating to human resources, should not underestimate their impact on companies to secure highly qualified personnel and top business executives as well as on employees' private lives (e.g. the issues of re-entry permit, sponsorship of domestic staff, getting a driving license, investing money in a pension fund).

Re-entry permit

The EU welcomes the Three-Year Plan for the Promotion of Regulatory Reform, dated 22 June 2007 and approved by the Cabinet, which states that the re-entry permit system should be reviewed by the end of FY 2007, and implemented at the latest before the entry into force of laws concerning the setting up of the new residence management system (Ordinary Diet Session of 2009). Foreigners living in Japan with a resident permission need to apply, whenever they leave Japan and for whatever purpose, for a re-entry permit in person, and in advance of departure, valid for the same period as the resident visa, but no more than 3 years. Moreover, all foreign residents are required to possess a resident permission in addition to the Alien Registration Card (*Gaikokujin-toroku-sho*). Therefore, the re-entry permit does not contain any unique information which would not already be registered somewhere else. Since a frequent travel activity is an essential part of many expatriates' working schedule, the EU suggests a swift abolition of the re-entry system.

Personnel with specific skills

European companies in Japan face difficulties in securing personnel with specific skills. The EU takes note of the efforts of the Ministry of Justice to

stimulate the inflow of workers possessing relevant skills. Relaxation of immigration laws is a first step. However, the EU would like to emphasise the need for increased recognition of foreign certificates and licences, not only in IT but in all areas, so that employees with certified special skills but lacking a university degree or ten years' working experience are also able to obtain a working visa.

Sponsorship of domestic staff

There is a shortage in Japan of internationally-aware foreign language-speaking childcare facilities; this may have an impact on the location decisions of international business. It is important that the rules related to the sponsorship of domestic staff be revised to allow a broader-range of business executives to sponsor staff taking full financial responsibility, with appropriate protections against abuse.

Driving licenses

The GoJ has agreed to fully recognise the driving license from 15 EU Member States. When residing in Japan holders of EU driving licenses have to exchange their European license to a Japanese one. However, holders of driving licence from the 12 EU Member states who joined the EU since 2004 have to undergo tests on driving capabilities. All EU driving licenses are issued under the same minimum requirements; therefore the GoJ should recognize all EU driving licences without differentiation.

Pension schemes

Foreign employees are obliged to pay into the Japanese pension system but in many cases will not receive benefits or a full refund at the time of their departure from Japan. The conclusion of bilateral agreements with Member States provides a solution, and the EU welcomes the conclusion of a number of bilateral social security agreements with EU Member States and the progress accomplished since last year. In the absence of bilateral social security agreements, refunds for departing foreign workers are calculated according to the length of their stay. However, foreign workers can only benefit from a partial refund system capped at 3 years. For this reason, many foreign workers only stay in Japan for 3 years. The EU would like to point out that some additional unilateral measures on pension schemes would help to offer more flexibility to personnel management. Departing expatriates should receive a full refund of all mandatory pension contributions paid.

The GoJ offers tax-exemption to Japanese citizens contributing to pension plans in Japan. The EU suggests that, in the upcoming proposals on taxation and tax reform, the GoJ considers to make financial contributions to foreign-based pension plans subject to the same tax-exemption made to pension plans in Japan.

Reform proposals

The EU requests the GoJ to consider the following proposals:

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

- a) To abolish the system of re-entry permits;**
- b) To allow a broader-range of business executives to sponsor domestic staff;**
- c) To recognise the EU driving licenses of 12 Member States who joined the EU since 2004 in the same way as driving licenses already recognised for 15 EU Member States;**
- d) To further relax the visa requirements as well as to recognise foreign certificates and licenses to meet the needs of European companies, especially regarding personnel with specific skills.**

II. Concerning pension schemes:

- e) To conclude bilateral social security agreements with all EU Member States as soon as possible;**
- f) For EU citizens not yet covered by a bilateral agreement with a view to avoiding wasted premiums and double pension costs:**
 - o To increase the cap for the partial refund of contributions to 5 years instead of 3 years as a first step towards allowing for a full remittance of mandatory contributions paid to the Japanese public pension system by foreign workers;**
- g) To ensure that contributions to foreign-based pension plans are subject to the same tax relief as contributions made to pension plans in Japan;**
- h) To improve, at the occasion of the upcoming tax reform, tax-exemption levels for optional contributions to pension schemes and allow possibilities to borrow against pension reserves.**

Other relevant dialogue: Investment-related issues were reviewed in the EU-Japan High Level Trade Dialogues in meetings in April and July 2007.

1.4 Transparency

Highlights:

Transparency is part of competition between global players like Japan and the EU: business regulations which are better understood will be more cost-efficient, public policy objectives can be met while minimizing the inconvenience for business and growth, and the risk of discouraging new investments may be minimised. However, consultation of interested parties can only supplement and never replace the procedures and decisions of legislative bodies which possess democratic legitimacy. The EU, which has been implementing an ambitious "Better Regulation Package" policy, is looking forward to a mutually enriching exchange of experience with Japan on this issue.

Case history: first raised in 2000, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

The public comment procedure

The Public Comment Procedure, which was set up in 1999, is one of the major instruments to promote transparency. Integrated into the Administrative Procedure Law since 1 April 2006, it provides a legal basis to ensure a general and uniform application across the GoJ and includes a standardised comment period of 30 days. Since no data is available for FY2006 at the time of drafting the 2007 RRD proposals, the EU cannot estimate how far the public comment procedure may fulfil its objective. It is important that the GoJ continues to monitor the development centrally and implements this procedure to draft directives/orders (*meirei*) in their entirety, and not only to excerpts or summaries, and ensures that the 30-day period for comments is respected.

No-Action Letter

The EU welcomes the Cabinet decision of 22 June 2007 that brings improvements to the No-Action Letter (NAL) system²: it broadens the scope of the NAL, it makes the name of the inquirer public only if he/she agrees and requests it, it gives the possibility to postpone the publication of the content of the inquiry itself beyond 30 days after the date of the letter. The EU believes that this Cabinet Decision may have a very positive influence on the business environment in Japan. The EU would be grateful to hear from the GoJ how various Ministries and Agencies, especially the Ministry of Finance and Financial Services Agency, intend to implement this new Cabinet Decision.

The EU would also like to draw the attention of the GoJ on an issue related to the confidentiality which can be raised in the NAL system. The fact that the decision taken in the NAL procedure is published on the internet prevents many

² The NAL system enables stakeholders to ask and receive information on a regulation from the competent Ministry (interpretation and scope of the regulation).

European businesses from using it effectively. This is particularly true in specific cases where anonymity would not ensure confidentiality as the matter is well known to the public (in contrast to cases with a common denominator often brought forward by overarching business organisations).

An example of a case where confidentiality would be desirable is tax-deferral in mergers & acquisitions (M&A). As the decision on certain transactions depends on whether tax-deferral will be granted or not, an advance ruling is very useful. Also because European companies believe that it increases legal certainty (contradictory to an oral assurance). However, advance publication, revealing the intentions of the applicant, could jeopardise the successful conclusion of a deal, as rival businesses would easily identify the parties involved. Therefore, either delay in or no publication could be a solution in such specific case.

Foreign stakeholders

The EU considers it important that foreign business has the opportunity to get access to information on draft regulation at an early stage, to present its valuable experience to regulators and be involved in the discussions about impact analysis and assessment of the draft regulation. In Japan, foreign business organisations should, in a general manner, be given better access to advisory councils (shingikai), study groups (kento kaigi) and similar consultative organs during the consultative process leading to possible new legislation. By doing so, issues of importance to European and foreign business could be identified at an early stage and addressed, thus avoiding difficult situations like the one created by the Article 821 of the Corporate Law.

Regulatory impact analysis

The Regulatory Impact Analysis (RIA), which is promoted by the OECD, is an effective instrument for more objective decision-making and enhanced fairness in assessing both positive and negative implications of change or new regulations. The EU welcomes the increased attention attached by the GoJ to RIA, as demonstrated for instance by the Government Policy Evaluation Act (GPEA) and by recent positive developments following the coming into force of the revised GPEA on October 1st. The EU welcomes the August 2007 guidelines issued by the Cabinet Office which require each Ministry to make public on the internet the results of RIA as well as the Ministry's decision related to the RIA results. It is important that the GoJ continues to strengthen its RIA policy. The EU would appreciate an update on the measures the Ministry of Internal Affairs has implemented under the framework of GPEA.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. With regard to the implementation of the Japanese Public Comment Procedure:

- a) To continue to publish the annual report to assess how far the Public Comment Procedure has been implemented by ministries and agencies, in particular for the 30 day comment period procedure;
- b) To make available for public comment complete draft directives/orders (*meirei*) rather than mere summaries before such drafts are submitted to the Diet for deliberation;
- c) To ensure that Ministries and Agencies will allow sufficient time to take into account, in the appropriate way, public comments when drafting new or changes of regulations, and continue to monitor the results.

II. With regard to the No-Action Letter:

- d) The EU would be grateful to hear from the GoJ how Ministries and Agencies, such as the Ministry of Finance and the FSA, intend or have already implemented the 22 June 2007 Cabinet Decision;
- e) To consider the possibility to include a confidentiality provision in specific cases either by not making the NAL publicly available before the transaction is done or at all in order to make the NAL procedure more effective.

III. With regard to the participation of European-affiliated stakeholders in the decision-making process:

- f) To adopt an horizontal policy, not on a Ministry-to-Ministry basis, more favourable to the involvement of foreign business organisations in Japan in advisory councils (*shingikai*), study groups (*kento kaigi*) and similar consultative organs.

IV. With regard to the use of Regulatory Impact Analysis:

- g) To extend the use of RIA to all fields of activity;
- h) To take into account public input while processing the RIA, not only in the cases where a public comment procedure is carried out.

2. Government Procurement

Highlights:

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

Despite some encouraging developments in Japan in the past, e.g. in the field of countering bid-rigging (kansei dango), certain features of the Japanese procurement system remain not enough transparent, open and competitive.

There is a perception in Europe that foreign bidders still face significant administrative and practical, if not legal obstacles to win public procurement contracts in Japan. Also a codification of the highly complex and fragmented procurement rules would make tendering more accessible, as would the central dissemination of all tendering opportunities (of central, regional and local tenders) via a central electronic gateway. A strengthening of transparency and predictability would encourage participation of EU suppliers. Currently, their virtual absence in many parts of the Japanese procurement market indicates that the effective market access opportunities are not currently perceived as viable.

Case history: first raised in 2003, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove major EU concerns.

Lack of transparency and predictability of procurement framework and process

The Japanese procurement legal framework is a complex system of statutes and regulations which are diverse and scattered across different legal texts. In general, central authorities' procurements are covered by the Accounting Law while sub central authorities' procurements are captured by the Local Autonomy Law. These laws date back to the end of 1940's but were substantially reformed several times since. Since these laws are often further supplemented by local by-laws, local rules on many aspects of the procurement conduct are not uniform.

For instance, local entities often do not conduct an evaluation of performance in cases of abnormally low bids, but set a minimum low price below which any tender is automatically rejected. Furthermore, this often does not take into account new technologies which allow lower prices. As a result, particularly efficient suppliers may be eliminated from the bidding process.

The difficulties in terms of effective market access created by diverse tendering rules between the central and local levels are further aggravated by the fact that only the 47 prefectures and 12 (out of 17) "designated cities" (*serei shitei toshi*) are subject to the WTO GPA rules.

Differences of approach between central and local procurement procedures are also reflected in the current fight against corruption and bid rigging in Japan. While the EU welcomed last year the revised guidelines published in May 2006 by the GoJ on "Promotion of Prosper Tendering and Contracting for Public Works", the EU continues to regret that these measures are only limited to certain central entities and do not apply to sub central entities.

Lastly, the EU notes that dissemination of procurement information in Japan is not satisfactory. Whereas central government's tender notices are all available (even electronically) in the national Gazette (Kanpo), local tender notices are published in various gazettes (Kenpo, Shiho or equivalent) and, where electronic, in an undetermined number of different electronic sites.

The EU regrets the absence of a single point of access in Japan equivalent to EU's own electronic centralised tender database "TED". The latter provides an instant overview of all tenders launched - or to be launched - for any member of the public in any of the EU's Member States and covers all government's level (central sub central, etc).

MLIT's certification of foreign experience

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

Business evaluation (keishin)

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

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

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

Compulsory registration before each procuring entity

In addition to the business evaluation, companies are obliged to register with each procuring entity. Registration is required every two years and there is no automatic renewal. In addition, the registration requirement is administered in parallel with the business evaluation process. The information required for the purposes of the registration procedure could be more efficiently collected either through the business evaluation, or through the actual submission of a tender.

The EU is of the opinion that this requirement places a disproportionate burden on suppliers. It is in contradiction with an efficient tendering system, especially where parallel administrative procedures require bidders to submit overlapping sets of information. The EU recognises that Japan started in 2005 to improve the system at central level only. These changes are not going far enough to remedy concerns raised by the registration process.

Technical specifications

Reports show that technical specifications are often too narrowly prescribed and do not allow bidders to bring any added value or innovative solutions. The EU has very positive experience of expressing technical specifications in terms of performance rather than design or descriptive characteristics, as incidentally also required under Article VI GPA.

In practice, this would mean that requirements, or references, for a particular trademark or trade name, patent, design or type, specific “origin, producer” or supplier would always be accompanied by words such as “or equivalent” in the tender document. Otherwise, procuring entities will not avail themselves of the full diversity of technical solutions available on the market. Thus, in order to be able to demonstrate equivalence, suppliers should be permitted to use any appropriate form of evidence, and procuring entities have to be capable of providing reasons for any decision rejecting equivalence.

Thresholds of public works contracts

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

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

Open and selective tendering

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

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

A systematic use of selective rather than open tendering procedures, as defined by the GPA, is a strong indicator that a procurement system is not fully 'open'. In the experience of the EU, such barriers to entry tend to facilitate collusive practices and lead to a loss of competitiveness.

Furthermore, it seems that central government entities are obliged to specify the criteria used for the designation of participants. On the other hand, local entities/governments do not seem to specify these criteria.

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

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

Award criteria

In open and selective tendering, contracts are almost systematically awarded in Japan on the basis of the lowest price (below a ceiling price). As a consequence, bid rigging between suppliers is facilitated and procuring entities tend to focus only on the price criterion instead of technical performance.

A radical change in the way of awarding contracts in Japan should be pursued. In particular, EMAT (economically most advantageous tenders) should be more systematically used, especially for awarding complex contracts. This shift would allow Japan to place more emphasis on quality and performance, through the introduction of effective and transparent evaluation/assessment schemes for tenders. For instance, criteria such as technical merit, quality, and cost effectiveness could also be examined in order to obtain a comparative assessment between price and technical merits (among others).

Furthermore, and as it is already the case in the EU, procuring entities in Japan should systematically publish in advance in the tender notice or the tender documentation, award criteria, their relative weighting and, where relevant, the method for assessing tenders.

Use of "operational safety" derogation in supplies procurement

Note 4 of Japan's appendix to the GPA allow Japan to exclude procurement awarded in the telecom or railways sector because of "operational safety" reasons. The EU regrets the extensive use of this derogation by Japanese procuring entities in particular in the railway equipment sector. Because of this extensive use, the EU notes that too many procurement operations in the railway sector are excluded from public tendering³. This situation is particularly worrying given that the EU railway supply industry amounts to 60% of world production and that the Japanese represents only 10%.

The EU is of the view that the apparent lack of penetration of the Japanese market is a direct consequence of the extensive use of this derogation.

The EU wishes to underline the importance it attaches to its request to delete this note in Japan's revised offer to the GPA. The EU considers that GPA already

³ Value of the procurement for railway market is estimated to 5.2 billion yen in 2005. This seems to be an extremely small amount compared to the domestic sales of the Japanese rolling stock industry (+/- 134 billion JPY in fiscal 2006).

provides exceptions to the Agreement for public safety reasons (see article XXIII), which all other GPA Members consider sufficient.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. Transparency and predictability of the procurement framework and process, including an easier access to procurement information

- a) To address the existing disincentives resulting from a disparate regulatory framework throughout Japan. The codification of the Japanese government procurement legislation could be an important measure in this regard, as it would achieve a more uniform set of rules between the central and sub central level;
- b) To make available all applicable legislation both at central and local level in English;
- c) To ensure that low priced tenders should not be automatically rejected by local procuring entities. Instead, suppliers should always be given the possibility to justify and explain the reasons for their pricing;
- d) To increase Japan's sub central coverage (Annex 2) under the GPA in order to ensure application of a more uniform set of rules by local entities;
- e) To set up a free of charge electronic single point of access where *a//* Japanese tender notices (central, local, etc) are published, as it is an essential way to enhance the competitive elements of the procuring process.

II. MLIT's certification of foreign experience

- f) In addition to the MLIT certification system, to ensure that foreign experience be recognised 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.

III. Business evaluation

- g) To eliminate the obligation for companies to undergo the business evaluation prior to tendering. In case the system is maintained, suppliers should have the choice that business evaluation regarding each specific procurement procedure is carried out centrally or by the procuring entities themselves.

IV. Registration system

- h) To eliminate the compulsory registration as far as public work contracts are concerned, or at least to replace the current requirements by a centralised registration at MLIT, valid for all procuring entities nationwide.**

V. Technical specifications

- i) To allow the consideration of innovative solutions as an alternative to rigid technical specifications. In this respect, it is important that procuring entities at all levels consider "equivalent" solutions which do not comply with the design or descriptive characteristics of the technical specifications, but do clearly meet the requirements thereof and are equivalent for the purpose or needs of the procuring entities in question. This applies not least with regard to "green procurement".**

VI. Thresholds

- j) To lower the thresholds for public work contracts by all procuring entities (central, sub central authorities) and to open up contracts to international competition by aligning new thresholds to international standards as accepted by the main GPA Parties (i.e. 5 million SDR).**

VII. Open and selective tendering

- k) To review the current legislation and practices on examination of qualification in open tendering procedures, to allow suppliers to tender without any prior check of their capacity.**

VIII. Award Criteria

- l) To consider substantial change in the way of awarding contracts and, in particular, a more systematic use, especially for complex contracts, of EMAT (economically most advantageous tenders). For instance, criteria such as technical merit, quality, and cost effectiveness should also be more frequently examined in order to obtain a comparative assessment between price and technical merits (among others).**

IX. Use of operational safety GPA note in the railway sector

- m) To review the current practice which relies too frequently on "operational safety exceptions" to exclude procurement from international competition in specific sectors. This is also in line with the EU's request to delete footnote 4 of Japan's appendix to the GPA.**

Other relevant dialogue: Procurement-related issues were reviewed in the EU-Japan High Level Trade Dialogue in April and July 2007.

3. Information and Communications Technology (ICT)

3.1 Strengthening the competitive safeguards to guarantee transparent, non-discrimination and cost oriented access to bottleneck facilities and interconnection.

Highlights:

It is essential that incumbent operators provide interconnection and access to bottleneck facilities according to the principles of transparency, non-discrimination and cost orientation, and make public the relevant terms and conditions. This requires additional transparency in the costs of the incumbent operator and the terms/conditions applied to its subsidiaries for those services.

Case history: recurrent issue, discussed in RRD in 2006. The Japanese reply delivered in September 2007 has not removed all EU concerns.

General comments

In 2006, the EU acknowledged on-going work on the principles of competition policy in the Internet Protocol era and future interconnection and pricing policy. The decision to exclude non-traffic sensitive costs from fixed interconnection charges was particularly welcome although a quicker implementation would have been preferable. However, interconnection charges seem to remain high; there are still concerns about access to bottleneck facilities from the incumbent operator at non-discriminatory terms and conditions; and a need to ensure fair interconnection to new IP-networks (Internet Protocol networks).

Terms and conditions for interconnection to the incumbent operators' network are critical for successful market opening in liberalized markets where incumbents control bottleneck facilities, retain high market shares and can leverage its dominant position into other markets. As convergence brings closer voice, data and audiovisual and allows for its delivery over increasingly robust Internet Protocol networks, a special vigilance is required to ensure a fair and transparent access to such IP-networks.

It is important that the Japanese Government ensures that the regulatory framework is effectively applied and ensures transparency of costs, provides for guarantees that charges to competitors are cost-based and prevents anti-competitive behavior regarding both the price and non-price terms of supply.

Reform proposal

The EU requests the GoJ to consider the following proposal:

- **To ensure that regulation stipulates that incumbent operators provide interconnection according to the principles of transparency, non-discrimination and cost orientation, and make public the relevant terms and conditions, especially regarding IP networks.**

Other relevant dialogue: the annual bilateral dialogue on Information Society between the European Commission and the Ministry of Internal Affairs and Communication (next meeting to be held in Tokyo on the 26th of February 2008).

3.2 Universal Service Financing

Highlights:

Both the EU and Japan are confronted with the need to guarantee the provision of a universal service in a changing environment. Japan has put in place a new financing scheme based on a Universal Service Fund. However it is essential that such a scheme applies exclusively to the net costs of the designated provider, is implemented in a transparent way and does not distort markets.

The EU would like to exchange experience and best practices with the Japanese Government on the universal service funding schemes and gain a better understanding of how the above mentioned principles are implemented in Japan.

Case history: first raised and discussed in RRD 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

General comment

The establishment of a fund financed by a broad range of operators as it is currently the case in Japan is one of the possible alternatives to finance the provision of universal service. The EU Universal Service Directive⁴ of 2002 also foresees the possibility for a National Regulatory Authority (NRA) to introduce a compensation mechanism from public funds and/or a mechanism where the net cost is shared amongst electronic communications providers if on the basis of net cost calculation the NRA finds that a universal service provider is subject to an unfair burden and the designated provider requests it.

However, as foreseen in the 2002 EU Competition Directive on competition in the markets for electronic communications networks and services⁵ there are certain principles that should be respected: any scheme serving to share the cost of universal service must apply exclusively to net costs, be based on objective, transparent and non-discriminatory criteria and be consistent with proportionality and cause the least market distortion. In addition when a sharing mechanism is established, its details and principles are to be made publicly available.

⁴ OJ L 108, 24.04.2002, p.51, "Directive 2002/22/EC of the European Parliament and of the Council of 7 March 2002 on universal service and users' rights relating to electronic communications networks and services (Universal Service Directive)".

⁵ OJ L 249, 17.09.2002, p.21, "Commission Directive 2002/77/EC of 16 September 2002 on competition in the markets for electronic communications networks and services (Text with EEA relevance)".

Calculation of the net cost

To avoid any market distortion the net cost for the designated provider must be calculated taking into account any market benefit. In the EU, Annex IV of the Universal Service Directive foresees that the net cost of universal service obligations is to be calculated as a difference between the net cost for a designated provider operating with the universal service obligation and operating without one. The calculation should assess all the benefits, including intangible benefits, to the operator (e.g. provision of other services on the same line, ubiquity, enhanced brand image, marketing and advertising sales, technical benefits from the extent of network, access to subscribers' data, life cycle value of customers and others). In addition, in the EU the accounts used for this purpose are to be audited or verified by the NRA and the results of the calculations must be made public.

Unfair burden

In addition, the NRA must evaluate whether the net cost really establishes an unfair burden, taking into account any intangible benefits, least market distortion and impact on the other operators on the market. Thereafter, and only upon request from the designated provider, compensation of the net cost can be provided via a public or a sector-specific fund.

Administration of the Fund

Furthermore, the sector-specific fund is to be administered or supervised by the NRA (if an independent entity is designated to administrate the fund). Contributions are to be unbundled and defined separately for each operator. Undertakings whose national turnover is less than a set limit may not be required contributions. Finally, an annual report is to be published providing the details of the fund's operation, including detailed information on the net cost calculations, contributions and market benefits.

While it is logical that different national systems have their own specificities (this is also the case in the EU), many of the principles described above are essential to avoid market distortions.

On the universal service funding, the EU would like to share information and experience to identify best practices with the Japanese Government and to improve understanding of how these or similar principles are implemented in Japan.

The EU would like to continue and deepen the discussion to gain a better understanding of the situation in Japan. The preparation by the European Commission of a forthcoming Green Paper on Universal Service will offer a unique opportunity for an exchange of experience and best practices with the Government of Japan on this matter.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To ensure that the implementation of its Universal Service Fund scheme allows only for the recuperation of the net costs incurred by the designated provider that constitute an unfair burden; is based on objective, transparent and non-discriminatory criteria; is proportional and causes the least market distortion;**
- b) To ensure that the accounts used for the calculation of the net cost and the burden incurred by the designated provider of the Universal Service are audited or verified by an independent authority and the results of the calculations are made public to guarantee proper transparency;**
- c) To share experience with the EU on the universal service funding to identify best practises and improve EU-Japan mutual understanding of how it is implemented.**

Other relevant dialogue: The annual bilateral dialogue on Information Society between the European Commission and the Ministry of Internal Affairs and Communication (next meeting to be held in Tokyo on the 26th of February 2008).

3.3 Global harmonization of spectrum for IMT-Advanced (systems beyond IMT-2000)

Highlights:

The absence of a globally harmonized spectrum for IMT-Advanced (International Mobile Telecommunications – Advanced) would create considerable technical barriers to international trade on related services and products: the need for local variations for telecommunication equipment will generate additional costs for its manufacturers, reduce economies of scale, result in higher prices for the consumers and render more difficult international roaming.

An agreement for a globally harmonized spectrum for such services at the next World Radiocommunication Conference (WRC-07) would be therefore highly beneficial for the EU and Japan.

Case history: first raised and discussed in RRD in 2007.

General comments

The next World Radiocommunication Conference (WRC-07) will be held in Geneva from 22 October to 16 November 2007. WRC-07 will consider spectrum requirements for the so-called "IMT" technology, which includes "IMT-2000", as well as "IMT-Advanced" (Agenda Item 1.4.) and will offer an opportunity for its global harmonization.

The European Commission will participate in WRC-07 together with the European Union Member States. The cooperation with the Japanese Government will be important in order to reach an agreement on a globally harmonised spectrum identification system for IMT - Advanced.

Reform proposal

The EU requests the GoJ to consider the following proposal:

- **To seek, jointly with other WRC-07 participants, a globally harmonised spectrum identification system for IMT-Advanced in the World Radio Communication Conference of 2007.**

Other relevant dialogue: WRC-07 will take place before the discussion of this year proposals in Tokyo, but we look forward to having the opportunity of assessing its result at the forthcoming bilateral dialogue on Information Society to be held in Tokyo on the 26th of February 2008.

3.4 Market access for telecom terminal equipment

Highlights:

Taking into account GoJ's initiatives in 2007 to strengthen the competitiveness of the domestic telecom equipment industry, the EU considers it important to pursue discussions in the RRD on a wider use of supplier's declaration of conformity to wireless radio equipment and to start an exchange of views on issues related to the mobile telecommunication equipment market.

Case history: for the issue related to conformity assessment, which was discussed in RRD in 2005, the Japanese reply delivered in 2006 has not removed all EU concerns. Blanket licensing and network neutrality are first raised and discussed in RRD in 2007.

Selected issues

The EU acknowledged in January 2004 the implementation by the GoJ of a new conformity assessment procedure- the Self Verification of Conformity (SVC) - in the telecommunication field. However, it needs to reiterate its concerns on the rather narrow scope of this system, which remains limited to wired telecommunication terminals and a part of wireless radio equipment.

Therefore, the EU would like to encourage the GoJ to extend the scope of SVC to wireless radio equipment as well as to fully accept the EU supplier's declaration of conformity (SDoC), as described in the EU's RTTE directive, without any additional requirements, for any EU telecom equipment import.

Following the release in July 2007 by the Ministry of Internal Affairs and Communications (MIC) of two reports- the mobile business study committee report and the network neutrality study, the EU would see mutual benefit to discuss with Japan on issues such as the impact of blanket licensing and of mobile operator practises (bundled offers and operator control on terminal accessing their services) on market access for mobile terminal equipment.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) SDoCs issued by European producers should be accepted in Japan without any additional testing or administrative requirements, not only for wired telecommunication terminals, but for specified radio equipment as well;**
- b) To extend the scope to SVC to wireless radio equipment;**
- c) To start exchange of views with the EU on issues such as the impact of blanket licensing and of mobile operator practises**

(bundled offers and operator control on terminal accessing their services) on market access for mobile terminal equipment.

4. Financial services

Highlights:

The EU welcomes the recent debate on how to revitalize Tokyo as a leading international financial centre and is very much looking forward the plan with concrete recommendations to be issued by the GoJ by the end of 2007, following recommendations from the study groups of both Council for Economic and Fiscal Policy and the Financial System Council. Based on its own experience, the EU would like to encourage the GoJ to liberalise further its financial markets and bring its regulatory framework into line with international best practice in order for Japan to achieve its full potential for growth and become a global financial centre.

Case history: first raised in 2000, discussed in RRD in 2007. The Japanese reply delivered in September 2007 does not remove all EU concerns.

4.1 Banking and investment services

The EU welcomes the entry into force of the Financial Instruments and Exchange Law (FIEL) on 30 September 2007. It considers that the FIEL is a positive step towards a more integrated financial industry in Japan and enhanced investor protection. The EU appreciates the fact that a grace period of up to six months, enabling domestic and overseas funds to continue operating without taking compliance steps on the condition that such funds were formed before the implementation of the FIEL and are sold after the implementation, has been set in order to mitigate the impact of the tightening of regulations. It also welcomes the Financial Services Agency's decision to exempt from the new law foreign funds with limited presence on the market.

Better Regulation

The EU would like to encourage the Financial Services Agency (FSA) to boost market vitality through better regulation and improved regulatory oversight. The EU experience shows that principle-based regulations foster market dynamism and the development of innovative products and solutions for the benefit of citizens in a context of ageing societies. By fostering innovation, better regulation will also help Tokyo to compete with other financial centres like Singapore, Shanghai or Hong-Kong. The involvement of stakeholders in the decision-making process is key to better regulation. The EU therefore encourages the FSA to work together with the industry, to develop clear codes of conduct and rules of enforcement.

Elimination of firewalls

The EU acknowledges the measures that have been taken to date to relax some of the firewalls which keep banking and securities operations separate (such as the authorisation of financial conglomerates as part of the "Big Bang" reforms initiated in 1998 and the possibility since 2002 for banks and securities companies to share common retail space). However, these measures have had a limited impact and Article 33 of the FIEL continues to prohibit in a general way commercial bank from engaging in securities business. Article 33 prevents financial services firms from offering their customers the full range of services, raises business costs, and forces international companies to adopt different organisational and management structures to any other major jurisdictions. For foreign groups, the forced separation of banking and securities activities is a major obstacle to the integration of Japan operations into their global business and a barrier to the development of new, innovative products. Article 33 of the FIEL is the largest single regulatory impediment to the development of Tokyo as an international financial centre, and is to detriment of the Japanese economy and of Japanese business and retail customers.

Based on its positive experience in universal banking, the EU believes that there are other ways of managing the risks stemming from potential conflicts of interest than through firewalls regulations. Efficient supervision and strict enforcement of internal control and corporate governance mechanisms prove to be effective ways of avoiding conflicts of interest and preventing malpractices.

The EU hopes that the GoJ will give adequate follow-up to the recommendations of both the Financial System Council and the Council on Economic and Fiscal Policy.

Liberalisation of trust banking

The EU regrets that no progress has taken place regarding the possibility for foreign bank branches to engage in trust banking. Trust banking reforms of 2002 allowing Japanese city banks to engage in trust and banking business concurrently have not been extended to foreign bank branches. Such prohibition is discriminatory and unjustified. The EU therefore repeats its request that the relevant legislative provisions be modified so as also to include foreign banks in the scope of definition. In the EU, concurrent operation of banking and trust business is possible in those countries of the EU where trust business is practised.

Full consolidation of rules and regulations governing the asset management industry

The EU welcomes the fact that, under the FIEL, the regulations regarding investment trust management firms and investment advisory firms have been consolidated, resulting in a single registration system as a Financial Instrument

Firm providing investment management services. However rules in detail applicable to those two categories differ in practice and they are under the supervision authority of both the Ministry of Finance and the FSA. Registration procedures differ depending on the scope of the application submitted. Although they are not very different, the businesses of investment trust management and investment advisory services require separate registration, filing and customer disclosure requirements, depending each time on the precise type of business the company is applying for. There is also broad discretion for processing applications under the registration system. The EU asks the GoJ to ensure a fully unified regulatory treatment for the asset management industry, as well as more consistency and transparency in the application process of the registration system. Moreover, the EU is hopeful that the Japan Investment Trust Association and the Japan Securities Investment Advisers Association will continue to strengthen their cooperation and therefore also contribute to consistency and transparency.

The EU notes with satisfaction that, as from 30 September 2007, an asset manager in Japan can place orders to buy or sell Japanese securities on behalf of its overseas group affiliate.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To finally abolish Article 33 of the FIEL which bans universal banking operation in Japan, as recommended by the Financial System Council and the Council on Economic and Fiscal policy;**
- b) To finally revise Article 1 of the law concerning Concurrent Management of Trust Business by Financial Institutions in order to eliminate discrimination and enable foreign bank branches in Japan to engage in trust and banking businesses concurrently as it is allowed for domestic banks;**
- c) To strive for better regulation in the financial services area, that is to say promote principle-based regulations and seek the close involvement of the financial industry in enforcing the rules;**
- d) To ensure more consistency and transparency in the registration system applying to asset management companies. Rules applying to investment trust companies and investment advisory companies should be fully harmonised under the supervision of FSA only.**

Other relevant dialogue: High-Level Meeting on financial issues between the European Commission and FSA.

4.2 Insurance

Highlights:

The EU welcomes the FSA plans to fully deregulate the sale of insurance products at banks. The EU requests the GoJ to suppress without delay the remaining restrictions applied to the sale of insurance products by banks. It encourages the GoJ to engage in solvency reform and to consider adopting methods being developed in the EU (Solvency II). It also reiterates its request to eliminate the differing treatment applied to regulated Kyosai.

Case history: first raised in 1999, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

Deregulation plan for the sale of insurance products by banks

The EU welcomes the report submitted by the FSA to the Financial System Council on 18 September which notes that the number of complaints filed concerning banks' insurance sales over the last two years does not justify any delay in the effective deregulation of bancassurance activities as from December 2007. Such a move will allow life, auto and health insurance to be offered by banks in addition to the limited range of savings-type products that they currently offer following the partial deregulation which occurred in 2001, 2002 and 2005. Based on its positive experience as regards bancassurance, the EU believes that strong supervision can efficiently prevent coercive sales practices.

The EU expresses its hope that full deregulation will take place within the foreseen timetable, in order to offer a better choice of insurance products as well as distribution channels to consumers. By full deregulation, the EU expects that no conditions will be attached to the sale of insurance products through bank networks that would reduce the impact of liberalisation. In the same vein, supervision and controls on the bank sales channel should be the same as for any other channel.

Reviewing solvency calculations

Enhancing the regulatory environment for the insurance industry is critical to future development. Japanese solvency calculation methodologies inhibit product innovation and are a misleading indicator for insurers' relative financial health. The use of market based solvency techniques, based on Solvency II, would result in more effective risk management and harmonisation with global best practice. The EU encourages the GoJ to engage in solvency reform and to consult extensively the industry in this respect.

Revision of the PPC scheme

The revised Insurance Business Law (IBL), which entered into force in April 2006, includes a revision of the current safety net for insurance policyholders (Policyholder Protection Corporation – PPC). The calculating method for financial contributions to the Insurance Policyholder Protection Corporation will be revised by FY2009. The EU is of the view that all companies which contribute to the PPC scheme should be involved in its design. Moreover, the current pre-funding method does not take into account the economics of specific product classes and potential risks to policyholders. Contributions to PPC's financial resources should be function of the risk of the product.

Regulated Kyosai

The amendments to the IBL also aim at imposing oversight on hitherto-unregulated *kyosai* (or mutual aid associations). While the EU welcomes the fact that these *Kyosai* will have to register as *small-amount short-term insurance providers* (SASTIP) and will come under FSA supervision as from April 2008, the IBL does not touch upon those *kyosai* that are established under other laws and are not regulated by the FSA but by other Ministries (such as agricultural cooperative and consumers' cooperative societies). Having millions of customers, these so-called "regulated" *kyosai* directly compete on the market as large-scale insurance companies. However, unlike licensed insurance companies subject to the IBL, the vast majority of these *Kyosai* are not required to contribute financially to the policyholder protection corporation, are not submitted to the same amount of corporate taxes nor the same solvency rules as their private insurance competitors, and are not submitted to FSA supervision.

The EU would like to stress again the necessity to bring *Kyosai* under the scope of the IBL in order to ensure a level playing field with the private insurance sector, especially if these *Kyosai* would be allowed to expand their business areas (as permitted by the new amendments to the Seikyo Law which were adopted in May 2007 and will enter into force in April 2008).

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To proceed with full-scale deregulation of insurance policy sales by banks as planned, i.e. by the end of 2007;**
- b) When reviewing solvency calculation methods, to consider adopting market based solvency techniques based on Solvency II;**

- c) To ensure that the future policyholder protection system to be set up is fair, non discriminatory and sustainable, i.e reflecting adequately the product features and potential risks to policyholders. Ensuring upstream consultation of the industry, including foreign insurance companies, in the process of reviewing the scheme of the Policyholder Protection Corporation is an important step in this regard;**
- d) To end the favoured status of Kyosai that are established under laws other than the Insurance Business Law by bringing them within the scope of that Law and submitting them to FSA supervision.**

Other relevant dialogue: High-Level Meeting on financial issues between the European Commission and FSA.

4.3 Auditing

Highlights:

The EU welcomes the amendments made to the Japanese CPA law (Certified Public Accountants Law) on auditing in June 2007, especially those addressing foreign auditors of third country companies. Discussions between experts from the European Commission and the Japanese FSA have been underway.

Case history: first raised and discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

CPA law

Given the recent adoption of the CPA law, which will be followed by the adoption in October 2007 of the Cabinet Order and the Cabinet Office Ordinance of the law, the European Commission services have not had the opportunity yet to fully discuss with the FSA the consequences for EU auditors of companies listed in Japan. However, the EU is confident that these legislative and regulatory breakthroughs set solid grounds enabling the FSA and the EU audit regulators as well as the European Commission to build sound cooperation.

Deepening bilateral cooperation in the field of auditing

Following Minister Yamamoto and Commissioner Mc Creevy's agreement in June 2007 on the necessity to enhance mutual understandings and co-operation in the area of auditing, including audit oversight systems, it has been decided that a final goal should be to move towards mutual reliance on each others' regulatory systems. Work will involve looking into many aspects, such as systems on quality assurance supported by adequate auditing standards, investigations and penalties, and public oversight.

On this basis, the European Commission and Japanese authorities have remained in contact and have collaborated to set up technical-level meetings between the FSA and the EGAOB (European Group of Auditors' Oversight Bodies). Such meetings, as well as bilateral technical discussions between the FSA and the European Commission, will take place at the end of November 2007.

Under the new 8th Company Law Directive on Statutory Audit, each EU Member State will have to set up a public oversight system to regulate auditors by mid-2008 at the latest. By mid-2008 also, Japanese auditors or audit firms of companies whose securities are listed in the EU should be registered with the relevant Member States' authorities where the listing takes place. However, Article 46 of the Directive foresees possibilities of exemptions from the registration requirement for third countries where public oversight systems

could be considered as equivalent, and if there are reciprocal working arrangements.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To ensure timely communication to the EU on the regulatory changes in Japan in the area of auditing, given the importance of moving towards equivalence of public oversight in the audit field;**
- b) To ensure that the constructive dialogue established between the FSA, the European Commission and the EU audit regulators can make progress on how to implement our respective legislation and develop an effective cooperative approach between our respective jurisdictions in the field of auditing.**

Other relevant dialogue: bilateral dialogue on auditing between the European Commission and the FSA set up in November 2006 (Next meeting to be held in November 2007).

4.4 Accounting

Highlights:

The EU strongly supports the convergence between international accounting standards and Japanese standards and in particular, the efforts of the Japanese standard setter (ASBJ) in setting up and adopting a time-framed programme to achieve convergence.

Case history: first discussed in RRD in 2007, further to inclusion of accounting issues in the Japanese RRD proposals in the past.

Accounting convergence

Regulation 1787/2006 and Commission Decision 2006/891/EC deferred the decision on the equivalence of third country Generally Accepted Accounting Principles (GAAPs) from 1 January 2007, for a further two years, until 31 December 2008. This means that third country issuers are exempt from the obligation to use EU IFRS or to restate financial information in accordance with EU IFRS until 2009.

In July 2007, the European Commission has provided a report to the European Parliament and the European Securities Committee, which focuses on the respective work timetables envisaged by national authorities of Canada, Japan and the USA for the convergence between International Financial Reporting Standards (IFRS) and their national Generally Accepted Accounting Principles (GAAPs). A second report is planned for April 2008.

Before 1 January 2009, the Commission will have adopted further legal measures regarding the definition of equivalence, the equivalence mechanism and the determination of which GAAPs are equivalent. The Commission consults the Committee of European Securities Regulators (CESR) on these proposals.

Whether or not Japanese accounting standards will be considered to be equivalent will most probably be decided mid 2008. We expect that Japan will increase its efforts towards convergence in order to facilitate a positive decision and we welcome the Tokyo Agreement of 8 August 2007, by which the Accounting Standards Board of Japan and the International Accounting Standards Board agreed to accelerate convergence between Japanese GAAP and IFRS.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To ensure that sufficient progress is made in the convergence process between Japanese GAAP and IFRS as a foundation for the important decision the EU has to take in 2008 regarding equivalence of third country GAAPs;**
- b) To ensure that everything is done to facilitate an acceleration of the convergence efforts undertaken by the Japanese Accounting Standards Board (ASBJ) in order to bring Japanese GAAP as close as possible in line with IFRS;**
- c) To encourage the ASBJ to set up an appropriate mechanism and structure in order to ensure that convergence is maintained for the period until 2011 and after.**

Other relevant dialogue: bilateral dialogue on accounting between the European Commission and the FSA.

5. Privatisation of Japan Post

Highlights:

The EU welcomes the first step of the 10-year privatisation process of Japan Post on 1st of October 2007 as planned.

Case history: first raised in 2002, discussed in RRD in 2006. The Japanese reply delivered in September 2007 partially removed EU concerns.

Privatisation process of Japan Post

Key to the success of the privatisation process will be the capacity to ensure a smooth transition without market disruptions, while ensuring a level playing field, including the equal regulatory treatment throughout the privatisation process, between the successor entities of Japan Post and its private competitors.

The EU welcomes the business plan announced on 27 April 2007 by the Japan Postal Services Corporation and the fact that public comments were invited on this document. Transparency in the Japan Post privatisation process is indeed vital to ensure that transition to the private sector will be conducted smoothly and fairly. At the same time, the EU regrets the fact that this public consultation focused on a "summary" which represents only a small portion of the full business plan.

The plan indicates that the Japan Postal Services Corporation will list Yucho and Kampo on the Tokyo Stock Exchange as soon as possible, the target being within 3 to 4 years from the start of the privatisation process (i.e. by 2011 at the latest). It also indicates that the completion of the privatisation process of Yucho and Kampo should take place within 5 years from the listing (i.e. by 2016). An early listing of the shares of the two postal financial services companies as well as an early completion of the privatisation process would be a positive step towards ensuring a better level playing field with private sector companies and fighting misperceptions on implicit government guarantees.

Eliminating perceptions of implicit government guarantee

According to the plan, Yucho and Kampo should be allowed to launch new products such as mortgage loans, credit cards and medical insurance soon after the start of the privatisation process, that is to say before they are listed. Such an early launch into new business operations poses a concrete problem of an implicit government guarantee to Yucho and Kampo. Sources say that Yucho could enter the mortgage business as early as next year. Mortgage business being a key segment for commercial banks' retail operations; this is likely to adversely impact the operations of private banks. Furthermore, details on

business expansion remain unclear. The EU would welcome some clarification on the exact timing and approval process for business expansion.

Ensuring open and fair access to the Post Office network

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

Opening up the mail delivery sector

The Ministry of Internal Affairs and Communications has recently announced plans to go ahead with the progressive dismantling of the mail delivery monopoly of the Postal Delivery Company, with some draft law expected in this respect by mid 2008. The EU welcomes this positive step which would allow new entrants into the mail delivery market by gradually eliminating the existing stringent requirements for private sector delivery (which include for instance the installation of 100,000 mailboxes nationwide).

Ensuring equal treatment of EMS with private express carriers

The Postal Delivery Company is expanding more and more into the international logistics market. The recent announcement of its collaboration with China Post in Express Mail Service (EMS) clearly underlines this intention. Such an expansion is problematic from the point of view of the principles of fair and sound competition since the Postal Delivery Company enjoys differing regulatory treatment compared to private express carriers. At present, Japan Post's EMS is largely exempt from transportation regulations (in particular parking rules under the revised Road Traffic Law) and security regulations (which call for non-inclusion of such dangerous or illegal objects in cargos such as explosive, radioactive or toxic substances, narcotics, etc.). It also enjoys preferential customs treatment. The Ministry of Internal Affairs and Communication (MIC) justifies such preferential treatment by considering EMS as falling under the universal service obligation. Being a competitive, value-added service, the EU considers that EMS should not be treated as part of the protected universal service and should be subject to the same laws and regulations, including all transportation, security regulations and customs laws, imposed upon private carriers. The EU welcomes the revised Customs Law which requires that all postal cargo valued in excess of 200,000 Yen be subject to the same clearance procedures as private express carriers. However, it notes that this measure has a very limited impact since the majority of EMS deliveries are below this threshold. Furthermore, there is no agreed timetable for the Postal Delivery Company to meet the current 10,000 yen limit which applies to private international express carriers.

Equal treatment of EMS with private express carriers also means that no cross-subsidisation should occur between the protected universal postal service, which will possibly benefit from the two trillion Yen social contribution fund, and EMS which is a competitive business.

Ban on domestic air freight forwarding business by foreigners

The Freight Forwarding Business Law was introduced in Japan to support an integrated freight forwarding industry utilising all different freight modalities (sea, land, railway and air). The law does, however, forbid foreigners (a person who is not possessing Japanese citizenship or a corporation based in a foreign country, or is foreign controlled) to engage in domestic air freight forwarding business. The restriction applies only to air freight. This implies that a European freight forwarder is allowed to transport shipments from customers' sites to the gateways on road and/or rail, but may not use air within Japan. For shipments from and to remote areas such as Kyushu, Hokkaido and Okinawa, this restriction is obstructing timely and efficient freight.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To ensure full transparency in the privatisation process and organise public consultations on every implementation measure of the Postal Privatisation Law. It is essential that public consultations be comprehensive, i.e. focus on the full text of implementation measures, and respect the minimum time of 30 days for comments;**
- b) To organise public offerings for Yucho and Kampo as early as possible;**
- c) To strongly limit the expansion of business scope for Yucho and Kampo until these two companies are fully privatised. It is important that the approval process for business expansion be transparent and fair, and take into account the impact on the private sector;**
- d) To take appropriate measures to inform the general public that Yucho and Kampo do not benefit anymore from any form of government guarantees;**
- e) To ensure that private banks and insurance companies are treated on an equal footing with Yucho and Kampo as regards access to the network of Post Offices for sales of their products. The conditions to access the network should be clear and public;**
- f) To go ahead with the progressive opening-up of the mail delivery sector;**

- g) To treat Express Mail Service as a competitive service, not falling under the universal obligation service, and therefore apply to EMS the same regulatory treatment which applies to private carriers. In particular the same customs clearance procedure should apply to all postal cargo, regardless of value, handled by Japan Post's EMS and by private carriers. Likewise, EMS should not be exempted from the parking law, as well as all traffic and security regulations implemented by the Ministry of Land Infrastructure and Transport;**
- h) To ensure that adequate regulations and controls will be established to prevent cross-subsidisation between the successor entities of Japan Post, and also between the protected universal postal service and EMS. In this respect, accounting separation between EMS and regular postal mail services should be established;**
- i) To revise the Freight Forwarding Business Law so as to allow foreign companies to engage in domestic air freight, on an equal footing with domestic companies.**

6. Transport

6.1 Air transport

Highlights:

The EU considers Japan as a potentially very important partner in air transport. Areas which can be identified as joint priorities for further strengthening cooperation, if conditions are right, include : a broad bilateral regulatory dialogue, covering issues related to security, including the treatment of liquids, safety, airport capacity, air traffic management and market access. The Commission is able to offer Japan on behalf of all 27 Member States a comprehensive framework for addressing these issues that is legally secure and sustainable. This requires the designation of the European Community in a legal agreement(s) with Japan as competent to negotiate these issues. Without such action, the current agreements between the EU and Japan cannot provide a legally secure basis for continuing cooperation.

General comments (for the Regulatory Reform dialogue)

The EU would like to acknowledge the Japanese replies under the Regulatory Reform Dialogue delivered in September 2007 in fields such as the deregulation of distribution, pricing and settlement of airfares, the broadened range of advanced purchase fares and various airport infrastructure issues. In spite of some progress, most of the regulatory issues mentioned in the EU 2006 RRD proposals still remain to be adequately addressed. Airline companies and consumers are still dissatisfied with the lack of transparency and competition for tariff filing, of liberalization of airport use and of restrictive conditions for investment.

The EU welcomes Japan's intentions to liberalise its aviation relations with key partners and is open to develop further cooperation. Current aviation agreements between Japan and EU Member States do not constitute an adequate basis for doing this. Restoring legal certainty in the EU-Japan air transport relationship is a crucial step in developing further aviation relations between the EU and Japan. The need to amend the bilateral air services agreements was raised by President Barroso when he met the Japanese Prime Minister in January 2007 and was raised again at the EU-Japan Summit on 5 June 2007. At the June 2007 Summit, Japan indicated that this issue will be addressed bilaterally with Member States. Member States are ready to engage in such negotiations with Japan.

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

The EU therefore looks forward progress to being made as a matter of priority in restoring legal certainty and predictability. This would pave the way for a closer and more productive relationship between the EU and Japan and allow us to move on to a broader and forward-looking co-operation agenda including on many other aviation issues such as security, safety, airport capacity, air traffic management, market access and related "doing-business" issues.

Case history: first raised in 1999, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove EU concerns.

Reform proposal

The EU requests the GoJ to consider the following proposal:

- **To amend the existing bilateral frameworks between Japan and Member States to include Community designation by launching the necessary practical steps as a matter of urgency. This step is crucial in order to pave the way to broaden and strengthen EU-Japan bilateral cooperation on a wide range of air transport issues.**

6.2 Sea transport (International Shipping)

Highlights:

The EU would like to raise a number of issues, which continue to be of serious concern for EU shipping companies in Japan.

Case history: first raised in 1999, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

Prior consultation system

As referred to in last year's EU reform proposal, the situation regarding the prior consultation system in Japan continues to be problematic in so far as shipping lines wishing to make small routine or major changes to their operations require prior approval from the Japan Harbour Transport Association (JHTA). Japan indicated in its reply last year that the system is based on agreements among private circles and that possible changes should therefore be discussed by these parties. However, this does not remedy the principal problem that the system lacks transparency and effectively gives the JHTA the possibility to prevent shipping lines from seeking alternative, competitive services on the waterfront. In addition, foreign shipping lines are not member of the JHTA, which comprises all other major waterfront businesses. The EU would also like to know more about the alternative consultation system, which Japan refers to in last year's reply, where JHTA is not involved in the negotiations.

Port costs

For EU shipping companies the port costs in Japan remain an issue as they are very high compared to international standards. Unfortunately, the Super Hub Port initiative of the Ministry of Land, Infrastructure and Transport (MLIT) has not yet resulted in lowering of the port costs. Initiatives such as the promotion by GoJ of local Japanese Ports as Asia Gateways in order to enhance shipments to and from these ports to other Asian countries create competition and improve the terminal cost structure, but should also be employed for larger terminals. More general initiatives to improving port cost structures would benefit consumers and industry, notably also Japanese industry. In this connection, it would be beneficial to allow foreign shipping companies, which carry approx. 70-75 % of Japan's containerized trade in and out of the country and have extensive international experience, to be associated to the GoJ's discussions on port development initiatives. Similar consultations are carried out by the EU with major shipping partners such as Japan, e.g. in relation to competition issues.

Terminal operations

According to information received by industry, despite the new legal framework put in place EU shipping companies also continue to face problems with respect to certain terminal operations in so far as lines still have to apply for a license to carry out these operations. The MLIT has agreed to process applications within two months after their receipt, but requirements such as minimum employment levels continue to prevent the effective functioning of this system. As a consequence of these problems, no foreign company has set up its own terminal handling operations in Japan to the detriment of competitive terminal operations. Guidance from the MLIT on how foreign shipping companies should proceed in this respect would be useful.

Bidding

The EU would also request that competitive bidding through open tenders is supported by the GoJ. Although changes to the Harbour Transport Law implemented in November 2000 do not specifically prevent subcontracting with multiple stevedoring companies at confidential rates, it appears that independent, regular and competitive bidding does not take place in practice in Japan.

Reform proposals

The EU requests GoJ to consider the following proposals:

- a) To ensure that the supervision of Japanese port operations is transparent, efficient and fair, and does not extend to involvement in routine business matters, so that shipping lines are given the possibility to procure port services on a competitive basis;**
- b) To enhance the dialogue with relevant European as well as other foreign shipping lines on opportunities for port development initiatives with a view to improving the port cost structure;**
- c) To further support the establishment of and give guidance on how to set up new, competitive terminal operations, including those operated by shipping lines themselves;**
- d) To further support competitive bidding for stevedoring services through open tenders.**

Other relevant dialogue: EU-Japan Maritime Transport Dialogue set up in February 2005 (Last meeting held on 12th October 2007).

7. Healthcare and Cosmetics

7.1 Pharmaceuticals & Vaccines

Highlights:

Acknowledging the need to address the great challenges healthcare systems are facing due to changes in demography and public finances, the European Union considers it essential that constructive and comprehensive dialogue between industry representatives and all public Japanese authorities affected by the issue of drug spending and related aspects of industrial competitiveness be strengthened. When reviewing and reforming the healthcare sector, it is essential to implement a comprehensive approach which takes into account aspects like innovation, shortened drug approval times, and adequate rewards for innovation as well as budgetary and public health issues.

The ongoing dialogue and in particular the Japanese government's efforts to foster the development of innovative medicines are welcome.

Case history: raised in 1999, discussed in RRD in 2006 (except for vaccines, first raised in RRD in 2007). The Japanese reply delivered in September 2007 does not remove all EU concerns.

The registration of clinical trials and of new drug applications

While taking into account regulatory reforms such as the establishment of the Pharmaceutical Medicine and Device Agency in 2004 (PMDA), concerns remain with regard to the processing and approval times for registration of clinical trials as well as of New Drug Applications (NDA). European firms still complain about the target review time set by the Japanese authorities and, in particular, the actual processing time, which is still considered longer than justified. The EU, therefore, would like to reiterate its support for the GoJ's commitment to continue streamlining the drug evaluation and approval process in Japan and reducing the time needed for processing NDA applications.

As regards the PMDA, concerns are still voiced concerning the adequacy of the raised fees and the only incremental improvement in drug assessment and services rendered by this body.

Protection of intellectual property rights

The EU supports considerations aimed at improving the protection time for data submitted for drug registration purposes. It would like to share its experience with the GoJ in this field: the EU's present protection regime, which is de facto 10 years (with an additional year in case of new indications), may be considered as an appropriate tool to reward innovative companies.

Vaccines

The European Union welcomes the Ministry's of Health, Labour, and Welfare announcement of addressing some concerns related to vaccines with an initiative called "Vaccines Industry Vision" dated of March 2007. This is an important step.

On the basis of available information, non-Japanese vaccines are hardly available in Japan, a fact which is difficult to understand given Japan's limited competitiveness in the development of new vaccines. The relative low market share of non-Japanese products gives rise to concerns related to market access barriers, including lack of transparency when it comes to the existing regulatory framework as well as to tender procedures. The EU is interested in hearing the GoJ's strategy in this field, which could bring Japan in line with the situation in all other nations of a similar economic development.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To continue to improve the quality, efficiency and time of the registration process for new drug applications and ensure that the fees for drug approval are adequate and reflect the services rendered;**
- b) To improve the environment for innovation, namely by extending data protection;**
- c) To establish an environment reflecting international state-of-the art practices with regard to vaccines approval, thus removing unjustified market access hurdles for innovative vaccines.**

7.2 Medical devices

Highlights:

Japan's rapidly aging population and rising societal expectations for quality of life necessitates innovative health technology to help deliver quality health care to the Japanese people. Regulatory reform should be further promoted to enable beneficial technological innovations to enter the market expeditiously, without compromising patient and user safety.

The EU welcomes the replies received from the Japanese government and the progress made in more closely aligning many regulatory requirements with the recommendations of the GHTF as a result of the Pharmaceutical Affairs Law (PAL) revisions in 2002 (that took effect in April 2005).

Case history: first raised in 2003, discussed in 2006. The Japanese reply delivered in September 2007 does not remove EU concerns.

Global Harmonisation Task force

Japan's continuing active involvement in global regulatory harmonisation activities such as the Global Harmonization Task Force (GHTF), and the adoption of its recommendations, where possible, is strongly encouraged.

Approval process

The EU welcomes the reform measures described in the Japanese reply of September 2007 to streamline the approval procedure of medical devices and improve its transparency (e.g. increase in the number of reviewers, consultation on clinical trials, publication of review reports). However, the EU is of the opinion that administrative guidance regarding implementation at detailed and technical level remains to be issued and/or clarified. The "device lag" of products marketed in Japan long after introduction in Europe and elsewhere remains essentially unchanged. In addition, due to costs, length of process, and uncertainty, there is a notable backlog of devices marketed elsewhere for which marketing applications have not been submitted in Japan

While welcoming reported progress made, manufacturers continue to report significant delays and difficulties as regards acceptance of foreign clinical data and other technical data, e.g., shelf life and accelerated aging tests. Such information has typically been provided to, and accepted by, conformity assessment bodies and regulators in Europe and the United States. Thus, the overall time until market entrance, including pre-marketing conformity assessment/safety review and pricing approval, remains significantly longer in Japan than in Europe or the United States.

Moreover, while the medical device industry accepted significantly increased review fees at the time of its creation, the Pharmaceuticals and Medical Devices Agency (PMDA) resources, especially as regards pre-market review and quality

systems auditing, have not yet been increased in line with needs. Overall pre-market review times in several categories of submissions have significantly increased.

Innovative health technologies

Many health technologies are characterised by short product life cycles and high innovation rates. In practical terms, a parallel, rather than sequential, handling of regulatory approval and reimbursement procedures in Japan could significantly reduce the time for market entrance, which is now one to two years, or even longer for some new products.

It is essential that GoJ implement measures to expedite the access, insurance coverage and payment of "new-to-Japan" health technologies and associated physician technical fees.

The EU would also like to reiterate the importance of ensuring that pricing and reimbursement policies are supportive of the innovation process and therefore aimed at stimulating continued investment in medical devices industry by both domestic and foreign producers and importers alike. It is important that Japan takes measures to encourage the participation of qualified investigators and centres in Japan in multi-national clinical investigations of medical devices.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To further implement regulatory reform by streamlining and improving the transparency of the product approval process, taking into account available global data, and applying sound science and risk benefit assessments in line with GHTF Guidance documentation. The EU encourages Japan to progress in harmonising its regulatory requirements with those of its major trading partners;**
- b) To align Japan industrial standard (JIS) related to medical devices with international standards (ISO and IEC standards) without additional national requirements. Such a policy would be consistent with the recommendations of the Global Harmonisation Task Force (GHTF) on the role of standards and should be matched by continuing efforts to promote greater understanding and flexibility in interpretation of data by PMDA reviewers;**
- c) To implement adequate measures to reduce the time for market entry for new health technologies by handling regulatory approval and reimbursement approval in parallel, and to improve access further for new products by accepting relevant**

supporting information that may be based on foreign clinical data;

- d) To adopt a pricing policy for new and existing medical devices without causing significant delays in patient access to new technologies. The EU urges the GoJ to ensure that its policies create incentives for continuing investment in research and development in beneficial new technologies.

Specifically, the EU recommends the GoJ to consider the following reform measures:

(A) Regulatory:

- e) ***Quality management system (QMS) audits:*** to introduce periodic audits of manufacturing facilities, covering all devices produced in those facilities, rather than product-specific audits;
- f) ***Mutual recognition of Quality management system (QMS) audits:*** to apply the principle of mutual acceptance of audit results from other GHTF founding members, with the view to reducing the burden and disruption of repetitive QMS audits to essentially the same standards (ISO 13485) by different conformity assessment bodies on the same facilities;
- g) ***PMDA pre-market review performance goals:*** to consult closely with industry, including European industry, on the development of significantly improved review performance goals for PMDA's next five-year plan;
- h) ***Protection of proprietary information:*** to take steps to ensure that any public disclosure of information by MHLW or PMDA regarding products approved for marketing does not lead to disclosure of proprietary confidential information;
- i) ***Stability and ageing test data:*** to provide revised guidance whereby marketing authorisations for medical devices may be issued on the basis of accelerated stability test data where those test methods have been validated in recognised scientific literature or by other reasonable and credible scientific evidence;
- j) ***Change control and notification requirements:*** to work with industry to develop guidance on changes in device design and manufacture which could clarify "partial changes" and "minor changes" and the relevant notification and review requirements. This is an important step to reduce review backlogs, and in recognition of the iterative nature of most medical device development.

(B) Pricing and Reimbursement:

- k) *Foreign average pricing (FAP):* to work with industry, including Europe-based industry, to develop an equitable, transparent, and predictable alternative to the current system of determining the prices of many medical devices on the basis of foreign market prices;**
- l) *Functional category modifications:* to develop a process whereby existing functional categories for certain orthopaedic and cardiovascular medical devices can be modified to more appropriately reflect product differences and advances in technology.**

7.3 Blood plasma

Highlights:

Although the EU shares the objective to ensure a stable and sufficient supply of blood and blood products, it has to be pointed out that the issue related of – to our knowledge – artificially low market shares of non-Japanese blood products on the Japanese market has not been resolved.

The EU is aware of the contacts between the Japanese government and foreign suppliers. The EU once more encourages the GoJ to mend the current situation which implicitly or explicitly favours domestic producers over importers, a tendency which is aggravated by the Japanese reimbursement scheme.

Case history: first raised in 2002, discussed in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To continue its dialogue with the industry on pricing and reimbursement of blood plasma derived products in order to allow an even playing field for domestic and foreign companies;**
- b) To finally amend or clarify (in a legally binding manner) the wording of the supply/demand provisions of the Blood Law in order to avoid any implicit and/or explicit bias in favour of domestic producers.**

7.4 Cosmetics

Highlights:

From March 2009 onwards cosmetic products with animal-tested ingredients cannot (with some exceptions) be marketed any more in the EU. Conversely, the EU has repeatedly raised with Japan the issue of acceptance of alternative (ie non-animal) tests.

Case history: recurrent issue, discussed in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

Animal testing – trade in cosmetics

The EU welcomes the clear commitment of Japan to accept alternative (non-animal) testing methods for cosmetics. In this regard, it is relevant that replacement of animal tests is essentially a two-step process: the (scientific) peer review of a validation study ("validation") and its regulatory acceptance by the regulator/legislator. Regulatory acceptance normally follows the results of validation.

The EU would appreciate that Japan clarifies if it can accept the European validation, in addition to the use of alternative tests validated by OECD. Moreover, the possibility of a formalised joint validation by the EU and Japanese bodies should be considered as a long term.

Reform proposal

The EU requests the GoJ to consider the following proposals:

- **To accept EU-validated alternative methods for regulatory acceptance or, for the long term, to consider a formalised joint validation by the EU and Japanese bodies. This would be an important contribution to avoid differing regulatory acceptance of alternative methods and speed up validation in the respective other region.**

8 Food safety and agricultural products

8.1 Food Additives and Flavourings

Highlights:

Japan does not accept the international list of approved food additives issued by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The EU reiterates its support to GoJ to take more into consideration the scientific evaluation carried out by the international standard bodies or the EU in order to speed up its domestic process of authorisation.

Case history: first raised in 2000, discussed in RRD in 2006. The Japanese reply does not remove EU concerns.

General comment

In 2002, the GoJ considering the importance of the food additives list for international trade, proceeded to consider the authorisation of some substances on a priority basis. This list of the substances includes 46 food additives and certain flavouring agents. A schedule indicating the foreseen deadlines for the approval of these substances was issued in 2005. As already mentioned in the EU 2006 RRD report, these 46 substances represent only a part of the large amount to be examined. The lengthy procedure of authorisation of food additives in Japan remains an issue of concern for the EU and an irritant for international and bilateral trade relations. The EU considers it necessary that the standards of use for common preservatives, such as sorbic acid, potassium sorbate and sulphur dioxide, should be reviewed by Japan, in the short term, in order not to penalise imported food. Moreover, the use of some additives or nutritional complements, such as the iodate salt, should be considered as acceptable under certain limits that the EU would like the GoJ to set.

Furthermore, the EU is concerned about the process put in place to carry out evaluation studies in Japan. It seems to be based on 'first in, first out' principle; this delays the procedure when a substance needs additional tests, since, while waiting to get funding for such testing, other food additives can not be reviewed. This might be one of the reasons why the revision process remains slow, causing delays on the deadlines.

Evaluations in the EU

As requested by the GoJ in its reply of September 2007, the EU would like to remind that relevant information on the EU data requirements and regulatory system, as well as evaluations done are available on the following European websites:

Legislation, Guidance, and other introductory documents:

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

Evaluations by the Scientific Committees:

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

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

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

Reform proposal

The EU requests the GoJ to consider the following proposal:

- **To rely on a greater extent on the scientific evaluation carried out by the international bodies such as JECFA and CODEX Alimentarius, as well as the information received from other partner countries, including the EU. This should contribute to reducing the cost of the studies, the duration and the human resources dedicated; as well as improving EU-Japan mutual understanding on scientific issues.**

Other relevant dialogue: This issue was raised at the Japan-EU High Level Trade Dialogue in April 2007.

8.2 Imports of Bovine and Ovine Products (Especially Beef)

Highlights:

The EU welcomes the fact that GoJ has sent to the requesting EU Member States the questionnaires to export beef and sheep meat.

The EU encourages the GoJ to align its national risk assessment policy and legislation with OIE guidelines and to evaluate the questionnaires sent back filled in by the Member States, in the light of the standards set by the above mentioned Organization.

Case history: First raised in 2005, discussed in RRD in 2006. The Japanese reply does not remove EU concerns.

General comment

The EU appreciates that the two Ministries (MHLW and MAFF) are already working on Member States' BSE risk assessment. The EU hopes that with the increase in demands by EU Member States, the GoJ will dedicate more human resources to deal with this new task consistent with the responsibilities that follow from membership of WTO/SPS.

In this respect, the EU would like to highlight that the World Organisation for Animal Health (OIE) issued a list of bovine products which can be safely traded, regardless of the BSE status of country, among which is de-boned skeletal muscle meat from cattle 30 months of age or less.

The EU is, moreover, concerned about the fact that it seems that the GoJ does not allow the EU Member States to process bovine products intended to be exported to Japan even if originating from countries BSE free.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) **To quickly process with the requests from all EU Member States who have applied for trade in bovine meat and did not yet receive any answer;**
- b) **To allow Member States to process bovine meat originating from BSE free countries for products intended to be exported to Japan.**

Other relevant dialogue: This issue was raised at the Japan-EU High Level Trade Dialogue in April 2007.

8.3 Organic Food Certification

Highlights:

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

Case history: first raised in 2005, discussed in RRD in 2006. The Japanese reply does not remove EU concerns.

EU concerns

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

Secondly, and of utmost importance, organisations which are already registered have to go through exactly the same procedure again as organisations applying for the first time, thereby facing excessive administrative and financial burdens. The EU requested that MAFF exempt currently registered organisations from the re-registration obligation or facilitate their re-registration at minimum cost and burden. However, this proposal was rejected by MAFF by letter of 8 August 2005 to DG AGRI.

The EU is concerned that the cost and administrative difficulties prevent EU certifying organisations from re-applying and seriously disrupt the supply of organic product from the EU to Japan.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To implement measures exempting certifying organisations already registered under the previous JAS law fully or partially from the re-registration procedure under the new JAS law;**
- b) To ensure that administrative burdens and financial costs for newly as well as already registered organisations be minimised in order to avoid discrimination in comparison to domestic organisations;**
- c) To finally clarify how countries having organic equivalency status with the Japanese system can have facilitated access to the Japanese market under to the new JAS law.**

8.4 Phytosanitary Regulations

Highlights:

The EU welcomes progress done in this field and encourages the GoJ to continue its work to extend the list of non-quarantine pests to the remaining organisms proposed by the EU.

Furthermore the EU would like to see some additional progress in the collaboration between the GoJ, the EU and its Members States when establishing import requirements/measures applied to Fruit and Vegetables be exported to Japan.

Case history: first raised in 1999, discussed in RRD in 2006. The Japanese reply does not remove EU concerns.

Japanese list of non quarantine pests

The EU welcomes the work conducted by the GoJ on the Pest Risk Analyses' response to the EU to add to the Japanese list of non-quarantine pests. The EU appreciates the fact that 4 pests (*Thrips tabaci*, *Tetranychus urticae*, *Panonychus ulmi* and *Brevicoryne brassicae*) have already been added to the list and that a further 3 pests (*Frankliniella occidentalis*, *Myzus persicae* and *Neomyzus circumflexus*) have recently been approved for plants intended for direct consumption (fruits and vegetables) and cut flowers.

Concerning *Aphis fabae* and *Aphis gossypii*, the EU would like to know when the GoJ, who is conducting Pest Risk Analyses, intends to approve the reclassification of these pests.

Access to the Japanese market for fresh fruits and vegetables

To export fresh fruits and vegetables to Japan, all the EU Member States have to agree on an individual specific Protocol; this procedure lacks flexibility. The EU welcomes the willingness of the GoJ to consider extending an approved protocol for one variety of a certain fruit to other varieties of the same fruit. Therefore, it invites Japan to collaborate with the Member States to identify evidence required to demonstrate the effectiveness of a protocol which has been approved for one variety of a fruit, so that it will be applicable for another variety.

We understand that the same species of pests may have different characteristics according to their habitats. However, the EU would like to point out that some regions in the EU are very similar to Japan in terms of climate and flora, therefore the EU invites the GoJ to consider the possibility of applying the same import conditions to Member States which have the same characteristics.

Concerning the level of systems/measures relating to export quarantine or domestic quarantine, all the Member States have to provide the same level of

protection that as laid down in the relative legislation. The bilateral consultations with individual EU Member States on the specific quarantine measures are indeed useful. In this respect, the GoJ should proceed by giving the Member State the chance to prove that a treatment developed for one country can be put in place in its own territory also.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To conclude the pest risk analysis on *Aphis fabae* and *Aphis gossypii*, in order to insert these other 2 pests in the list of non-quarantine organisms as soon as possible;**
- b) To start collaborating with EU Member States in order to apply approved protocols for one variety of a certain fruit to other varieties of the same fruit, such as the low temperature treatment against Med Fly which was approved, so far, only for Italian sweet oranges;**
- c) To allow EU Member States to prove the effectiveness, in their territory, of protocols already established for another EU Member State, with similar characteristics. In this regard, for Japan to consider using protocols already established for one EU Member State as a model for similar protocols with other Member States having similar characteristics (in terms of climate, flora, etc) should be an important step;**
- d) To proceed with the requests from all EU Member States who have applied for export fruit and vegetables and have not yet received any answer;**
- e) To ensure that the EU Member States may have an easy access to the results of the Japanese Pest Risk Analysis carried out for their country.**

8.5 Breeder's rights

Highlights:

The EU recognises the significant efforts made by the GoJ to step up the control of possible infringements of breeders' rights. The EU recognises also the measures taken by the GoJ to limit the use of the farmers' privilege by additionally designating 58 genera or species as those that are not subject to the farmers' privilege exemption. The EU notes however that none of the species suggested by one Member State are yet included since the last Regulatory Reform Dialogue. Therefore, the EU invites the GoJ to enlarge the scope of plants genera or species to which the farmers' privilege exemption does not apply and to include the species mentioned living up to the rules as laid down in the UPOV.

Case history: first raised in 2005, discussed in RRD in 2006. The Japanese reply delivers in September 2007 does not remove all EU concerns.

Reform proposals

The EU would like the GoJ to consider the following proposals:

- a) To continue discussions with stakeholders in Japan and step up controls of infringements;**
- b) To enlarge the scope of plants genera or species to which the farmers' privilege exemption does not apply and to include the species mentioned living up to the rules as laid down in the UPOV.**

8.6 Regionalisation

Highlights:

The EU acknowledges that the GoJ, by its reply of September 2007, agreed to discuss with relevant experts the disease control system in the EU and the establishment's procedure, in order to find a pragmatic process to achieve regionalization within the shortest delays. Therefore, the EU encourages the GoJ to start these consultations as soon as possible.

Case history: first raised in 1999, discussed in RRD in 2006. The Japanese reply delivers in September 2007 does not remove all EU concerns.

General comments

The EU acknowledges that Japan has applied regionalised trade restrictions to EU Member States, in accordance with the OIE principles

The EU also notices that according to the GoJ since the disease prevention systems and the technical levels of administrative authorities differ among EU Member States, the GoJ believes that bilateral consultations with exporting countries are essential to understand the actual state of their systems and technical levels in detail.

In this respect, the EU would like to point out that all the sanitary measures put in place are decided after several discussions between the EU and the Member States experts and are laid down and formalized by the Council Decisions. Therefore all EU Member States measures provide equal guarantees.

While the EU welcomes the bilateral negotiations between the Member States and GoJ, it has some major concerns with the practical application of regionalization and the length of the evaluation process. This, in particular is the case for the size of the zones approved by the GoJ that are often significantly bigger than found necessary by the European Commission and Member States.

The EU would like also to highlight that although the GoJ does not carry out studies on all the EU Member States, animal health in the EU is constantly under control. All the Member States have in force monitoring plans and put in force eradication plans when necessary. Therefore, the EU would like the GoJ to refer to the areas or zones when requiring the free disease status in the official certificate and not to the whole country.

Establishment's working procedures

The EU is concerned about the restrictions in the working procedures to be adopted by the approved establishments when processing products, in a regionalized country, intended for the Japanese market. In this respect, the EU considers that the requirement not to process any meat originating from the

areas or countries not recognised as free by GoJ is indeed excessive. The efficient tracing system (in place during all the processing steps) and the different scheduling of the processing operation certified by an official veterinary officer should be enough to guaranty the compliance of the final product with the Japanese requirements.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To revise the criteria to be applied in case of the definition of the Member State' region or zone to be regionalized, and to consider the reference to areas or zones when requiring the free disease status in the official certificate and not to the whole country;**
- b) To revise the current risk analysis procedure with a view to relying more on EU sanitary measures and to improve the evaluation process to reduce the delays;**
- c) To revise its requirements on working procedures to be adopted in case of regionalization, in the EU establishments processing products intended for the Japanese market, with a view to mitigating the restrictions.**

8.7 Import Controls - Appeal procedures

Highlights:

Both the EU and GoJ recognise the need for consumer protection and are both concerned about non conformity with standards in imported food, nevertheless the EU has a different approach to the problem. In the EU legislation an appeal procedure is granted. The EU asks GoJ to consider using the EU approach and to respect international standards.

Case history: First raised in RRD in 2007.

General comment

The EU acknowledges that the GoJ, in compliance with the Japanese Food Sanitation Law, Art. 25 - Chapter 7, does not accept any objection under the Administrative Appeals Law, to the result of the examination carried out to prevent food hazards. The EU understands that the analytic control is aimed at protecting public health and considers it absolutely legitimate and indispensable. Nevertheless the lack of any possibility of appeal does not reflect the SPS Agreement Annex C parag. (i) according to which "*a procedure exists to review complaints concerning the operation of such procedures and to take corrective action when a complaint is justified*". Furthermore, it appears unjustifiable since it does not have any benefit for human health as the consignment would be blocked until the second analytic result. For comparison, Regulation guarantees adequate consumer protection and the EU is fully in line with international practice.

Reform proposal

The EU requests the GoJ to consider the following proposal:

- **To revise art. 25 Chapter 7 of the Japanese Food Sanitation Law to restrict its scope to genuine food safety concerns, and to include an appeal procedure when food contamination is found in imported food in order to align its national legislation with the principles of the WTO/SPS Agreement.**

8.8 Import controls

Highlights:

The EU acknowledges that the GoJ, in compliance with the Japanese food sanitation Law, checks 100% of the consignments in case of two consecutive incidents of non-compliance with the MRLs fixed in Japan, which seems to be more trade restrictive than necessary. In the 2007 RRD, the EU would like to raise this concern.

Case history: first raised in RRD in 2007.

General comment

The EU considers that the extension of the 100% controls to all the companies located in the same country from which the non-compliant imported goods were obtained, seems over reactive. In most cases, the products can be traced back to individual companies. In such cases a country-wide ban is not justified by public health considerations.

The EU considers that the Japanese practise to put under control a whole EU Member State after two infringements represent a lack of confidence in the EU surveillance system. Furthermore, the extra checks imposed on companies that had never had problems in complying with Japanese standards do penalise companies other than those involved in the incident.

Both the EU and the GoJ aim at a high level of consumer protection and are both concerned about non conformity of imported food. However, the EU does not apply sanctions against companies which have not contributed to the problem. The EU would like the GoJ to rely more on EU Member States surveillance authorities when pursuing consumer protection, and to apply a more proportionate measure.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To revise its current practice on border checks when MRL violations are found. In particular, it is important that the GoJ start consultations with the importing Member State at an early stage to limit to the minimum the 100% testing cases;**
- b) To accept the guarantees on the corrective actions taken, as issued by the local sanitary authorities or the companies and to remove the 100% testing requirement as early as possible.**

8.9 Casings

Highlights:

The EU has already indicated its interest to find a common solution for the issue of requirements for exports of hog casings to Japan. The EU draws attention to the fact that the requirements for US casings, where BSE also exists, are significantly less restrictive than for EU Member States.

Case history: first raised in RRD in 2007.

General comment

It is essential that the GoJ finds out an agreed solution with the Member States to modify the following certificate requirements.

On animal health, so far, when reference is made to animals, meat or casing imported, from another EU Member State in the processing country the GoJ asks general guaranties on "freedom from any infectious disease". This in order to consider safe from an animal health point of view the product intended to be processed for the Japanese market.

With reference to the establishment's working procedures, so far the GoJ imposes the obligation not to process natural casings derived from ruminants which have been born and raised in countries listed in a government document on the health requirements for natural casings to be exported to Japan.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To abandon the general requirement "freedom from any infectious disease" and accept the guaranties given by the result of the ante mortem and post mortem inspection;**
- b) To consider that the efficient tracing system (in place during all the processing steps) and the different scheduling of the processing operation certified by an official veterinary officer should be enough to guaranty the compliance of the final product with the Japanese requirements.**

9. Wood standards

Highlights:

The continuing demand in Japan for wood-based construction in the family home and other market segments has traditionally been supplied by both Japanese domestic production and considerable imports from third countries, including the EU. Nonetheless, the latter's supply of these goods to Japan could be further facilitated in certain cases by still better accommodation of EU wooden construction goods under the Japanese standards for wooden construction materials and products and the Japanese Building Law. The EU is committed to pursuing these issues with Japan through bilateral expert dialogue.

Case history: first raised in 2003, discussed in RRD in 2006. The Japanese reply delivered in September 2007 does not remove all EU concerns.

General comments

EU producers have supplied wooden building components to Japan for a number of years, not only for sawnwood but also glue-laminated beams ("glulam") and more recently composite wall and other panel units. The increasing supply of sustainably grown wood and growing wood-processing capacity in the EU have under-pinned the steady growth of these trade vectors and offer further potential.

Most of the relevant product standards are Japanese Agricultural Standards (JAS), run by the Ministry of Agriculture, Fisheries and Forests (MAFF) and some Japanese Industrial Standards (JIS), whilst the Ministry of Land, Infrastructures and Transport (MLIT) is responsible for the Building Law. Within these, consideration should be given to emerging EU wooden building products and systems which inter alia take specific account of fire and earthquake aspects which are so important in Japan.

In this context, the EU notes with satisfaction the continuation of the Wooden Building Experts' Dialogue (WBED), set up in 2006 between the European Commission services and MLIT, with EU industry participation. The first meetings have provided a useful and important forum to exchange information on market trends and best technical practices for wooden construction products and systems, as well as research and technical development and to identify potential areas for collaboration. The third meeting was held in October 2007 in Brussels, back-to-back with the first meeting of a working group chaired by MAFF on the status of European White Spruce (*Picea abies*). The latter meeting also proved very useful.

Reform proposals

The EU requests the GoJ to consider the following proposals:

- a) To consider the results of the first meeting of the working group on European White Spruce, together with subsequent information from the EU side, with a view to recognising and accepting European Spruce (*Picea abies*) as a separate tree and timber species from other spruces in the JAS glulam standard. Accordingly, based on the available test data for European White Spruce, it should be granted a considerably higher classification than at present in the wood-class classification;
- b) The empirical rejection within the JAS of wood types based on regional considerations should not be a reason to reject European White Spruce (*Picea abies*). The term "European" is not merely the indication of a geographic source, but moreover the term refers to a botanically distinct and identifiably separate tree and timber species, having measurably better wood performance characteristics than many other spruce species;
- c) To review the "Guideline for Designating Standard Strength, etc. of Lumbers, etc" (製材等の基準強度等の指定手続きガイドライン) to ensure that the EN standards and CE marking of Structural Lumber and Glulam can be recognised under MLIT Notification 1452 (2000) and - MLIT Notification 1024. (2001), respectively. This is crucial for the EU since some standards of competing exporters (WCLIB* marking being one example) have already been accepted under the scheme;
- d) To review the fire-endurance tests and fire regulations so as to allow the import of innovative, large-scale wooden products and systems, as well as fire-resistant materials from Europe. In particular, the 3+1 hour testing method should be reconsidered as it inherently disfavours wooden material – even though it is commonly understood that, in the case of fire, wooden structures will last in place as long or even longer than structures made of other materials, thus allowing safe escape from a fire for a longer period;
- e) To consider ways to simplify the accreditation procedure for testing organisations under the JAS/JIS (Japanese Agricultural/Industrial Standard) and Ministerial Approval Schemes, so as to provide a treatment no more rigorous than for other standardisation schemes. In particular, internationally accepted data (such as ISO accreditation data) and documentation in English should be accepted in the application to become a JAS-Registered Certification Organisation;

- f) To review the current test methods regarding secondary wood-based products (such as flooring, doors and windows) in order to facilitate testing for products imported from the EU to be used in multi-storey buildings.**

* West Coast Lumber Inspection Bureau

Other relevant dialogue: Wooden building experts' dialogue between the European Commission and the Japanese Ministry of Land, Infrastructure and Transport.

10. Animal health products

Highlights:

While taking into account Japan's efforts to harmonize its standards with international practices, the EU would like to reiterate its concerns on the product approval process for new veterinary medicinal products. It remains more cumbersome than necessary and delays the introduction of products or even prevents foreign manufacturers from introducing innovative products into the Japanese market. This is prejudicial for the Japanese livestock industry, the consumers of products of animal origin and pet owners.

Case history: first raised in 2001, discussed in RRD in 2006. The Japanese reply does not remove all EU concerns.

Listing system for antibiotic and other feed additives

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

Reform proposal

The EU requests the GoJ to consider the following proposals

- **To switch from a compound listing system to a brand-specific listing for antibiotic and other feed-additives. Japan's current system puts generic producers at a considerable advantage by enabling them to get a free on the investments and developments by manufacturers of original products.**