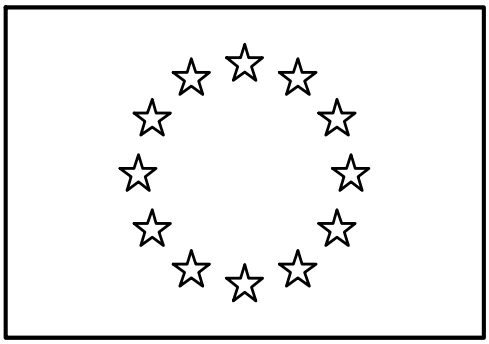
2 October 2008

EU Proposals

for Regulatory Reform in Japan

Final consolidated version



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2 October 2008

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Introduction

The European Union continues to attach considerable importance to its Regulatory Reform Dialogue (RRD) with Japan and to appreciate Japan's sustained commitment to this process. The EU also welcomes Japan's declared wish to make the dialogue more effective and efficient, in line with the outcome of the 17th EU-Japan Summit which took place on 23 April 2008 in Tokyo. The EU stands ready to work closely with Japan towards this end.

As the RRD enters its fourteenth year, against a more sombre and uncertain backdrop for the global economy, the case for pursuing regulatory reform efforts, both in the European Union and Japan remains a powerful one. In any event, the European Union trusts that the new Japanese government will pursue and intensify efforts to apply principles of "Better Regulation" and to promote Foreign Direct Investment, building on the work of previous governments in both regards, including since the last RRD High-Level Meeting in Tokyo (December 2007). During this period, the EU has noted the publication of the Report of the Expert Committee on FDI Promotion Report in May 2008 and welcomes the subsequent Cabinet Decision of 27 June 2008 announcing a comprehensive study of foreign direct investment regulations. The European Union stands ready to share its experiences with the Japanese government in this context.

CHANGES IN THIS DOCUMENT COMPARED TO 2007

Similarly to last year, the present document identifies priorities for the European Union to be discussed with the Japanese partners in the High Level Meeting to be held in Tokyo on 12 December 2008. Reflecting developments over the past 12 months, it lists 13 priority fields and the related EU regulatory reform proposals which the EU side would like Japan to address. It also includes requests from the EU intended to foster better understanding of the Japanese policy, approach or regulatory framework, e.g. on taxation, customs and maritime affairs.

Concerning deletions, the EU has omitted the RRD chapter related to sea transport, given positive feedback received from the EU shipping companies in Japanese ports on the improved business situation. As necessary, the concerns formerly raised in the RRD context could be discussed in the "structured regular maritime transport policy Dialogue" set up between the Commission services and the Japanese Ministry of Land, Infrastructure and Transport (MLIT).
Some EU proposals formerly addressed in the chapter on food safety and agricultural products have not been included in this framework but should be further discussed in bilateral meetings in the margins of WTO SPS meetings

(e.g. the EU RRD proposals on import controls including appeal procedures, hog casings).
With regard to the chapter on government procurement, the EU will pursue discussions on the RRD issues of the very high Japanese public works thresholds and access to public procurement of local Authorities in bilateral discussions with Japan in the margins of the WTO GPA negotiations.

Concerning issues added, greater focus was put on investment, taxation, corporate governance and Better Regulation. The issue of motor vehicles (chapter 8), which was last addressed in the RRD context in 2006, has been reinstated and now includes new regulatory aspects. A new chapter 7 on maritime affairs has been included with a view to deepening the EU understanding of the Japanese regulatory policy and sharing experience in this field. Furthermore, a new chapter on customs (chapter 9) has been inserted, highlighting the importance to achieve mutual recognition of Authorised Economic Operators Programs on a sound legal basis.
Moreover, two new issues of particular interest for the EU were added to the chapter 11 on food safety and agricultural products - listeria and the developments in Japan on traceability in the light of ongoing reforms of the Japanese framework on consumer safety and protection.

1 - Investment

1.1 FDI - Corporate restructuring – Corporate governance - Taxation

Highlights:
The EU welcomes the Japanese governmental priority to revise the "Program for Acceleration of Foreign Direct Investment in Japan (FDI acceleration program)", announced in the "Basic Policies 2008" document. However, while taking into account efforts to support FDI in Japan, even if Japan achieves its target of an FDI base of 5% of GDP by 2010, it will remain well below inward investment figures into the EU.

Case history: first raised in 2005, discussed in RRD in 2007. The Japanese reply delivered in December 2007 does not fully remove EU concerns. Investment in airport infrastructure, good corporate governance and some taxation issues are first raised in RRD in 2008.

General comments on the Japanese policy related to FDI

The EU welcomes the announcement by the GoJ of a revision of the Japanese "FDI acceleration program" in the context of the Cabinet Decision of 27 June 2008, which endorsed the 2008 program of economic and fiscal reform ("Basic policies 2008"). The official target of bringing FDI level to 5% of the Japanese GDP remains an important objective, given that the FDI level in Japan is less than one tenth that of other G8 Members. So far, progress has fallen short of expectations.

Under the "Basic Policies 2008", the EU notes that a "comprehensive study of foreign direct investment regulations" should start from Autumn 2008. It would like to invite the GoJ to clarify the scope and goal of this study and encourage it to take into account foreign experiences on FDI regulations. In this regard, the EU is ready to share its experience in this field.

Foreign ownership of airport firms

After forgoing an introduction of restrictions on foreign investment in airport-related companies this spring, the Japanese Ministry of Transport plans to sort out opinions by the year end and submit a bill to revise the airport law to the Diet next year. The EU understands that the Ministry considers that a cap on foreign investment would be contrary to the principle of non-discrimination between domestic and foreign investors; and that Narita International Airport Corp will not go public before the modified law enters into force (see also chapter 6 on air transport).

Cross-border mergers and their tax-treatment

In May 2007, it became possible for foreign companies to also use their shares – instead of cash - when acquiring a company in Japan: the new Corporate Law entered into force, 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). The move was considered with great hope. But one year later, with only one case, the current triangular merger scheme seems to remain too complex to be really attractive: a foreign buyer has to set up a Japanese subsidiary, if none exists, which is too cumbersome.

Allowing cross-border triangular mergers to benefit from tax deferral on capital gains (in the same way as is permitted for domestic corporate reorganisations between Japanese corporations) is an important step towards 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 Order of the Ministry of Finance set out the criteria to be fulfilled in order for such a subsidiary not to be classified as a 'paper company'. It is not clear whether this creates the desired legal certainty. It is not clear either whether possible investors consider as efficient the current advance inquiry system of the National Tax Agency (NTA) that is designed to answer questions related to tax treatment, for instance on individual mergers.

In its Report of 19 May 2008 Five Recommendations toward the drastic expansion of Foreign Direct Investment in Japan, the Expert Committee on FDI Promotion, chaired by Professor Shimada, mentions studies of system and taxation concerning M&A measures, including the expansion of the range of options. Indeed, expansion of the range of options would benefit the M&A market in Japan. If transactions like reverse triangular mergers[2] or stock-for-stock exchanges were possible under Japanese law and tax-deferred, it would substantially reduce costs which presently discourage FDI.

Mergers and acquisitions in sensitive sectors

In September 2007, the GoJ expanded the scope of sectors which fall under the notification requirement for mergers and acquisitions in sensitive sectors (according to the Foreign Exchange and Trade Control Law and the amended Ministerial Order) to include defence technology related sectors. In the RRD High Level meeting of December 2007, the Japanese side indicated that it would observe the principles of predictability, transparency and proportionality

[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.

[2] The target, not the Japanese subsidiary, is the surviving entity, which may be preferable or essential for licensing, regulatory and other tax-related reasons.

when implementing the law. In this respect, the two issues below illustrate some of the continuing EU concerns on how to ensure that the predictability and the proportionality principle are duly implemented:

* On 2008 May 13, METI, for the first time officially ordered a foreign company on the basis of the Foreign Exchange and Trade Control Law to discontinue a notified investment (the Children's Investment Master Fund –TCI- was ordered to discontinue inward direct investment related to the further acquisition of shares of J-Power).

* The EU would like to understand the motivations for choosing as a notification ceiling the figure of 10% of the stocks of a company active in a sensitive sector.

The EU would like to reiterate its request of a clear definition of the scope of sensitive ectors concerned by the notification requirement.

Corporate governance

The EU recognises the value of initiatives undertaken so far to strengthen corporate governance. However, the scope and impact of such initiatives remains limited, particularly as regards the protection of minority shareholders.

Constantly growing since 2003, the number of listed companies that have adopted poison pills schemes has reached 500 in 2008: one in eight.

Former Prime Minister Fukuda qualified defence measures against takeovers as 'excessive' during a meeting of the Council on Economic and Fiscal Policy (CEFP) that took place on May 20. As a clarification of the rules through case law would take too much time, the Cabinet Decision of 27 June 2008 mentions a "clarification of M&A rules by the summer".
In this context, METI has published in June an important report, "Takeover Defence Measures in Light of Recent Environmental Changes", which takes the premise that takeover defence measures are for the protection of the interests of shareholders, and not for the purpose of managerial entrenchment, and that the final judgement on the takeover should be made by shareholders.

The Tokyo Stock Exchange (TSE) is also making efforts to strengthen the protection of the rights of shareholders. It is seeking input from investors on the best ways to improve corporate governance in Japan and the well-publicized warnings of Chairman Saito are also going in the right direction.

But neither METI nor TSE seem to be contemplating compulsory guidelines, contrary to some other exchanges in the EU, such as the London Stock Exchange.

The EU believes that the steps taken to date go in the right direction but do not yet address all the important issues such as:

- **Implementation of the poison pill scheme**: METI's report mentions that, in cases where a special committee is established as a measure to gain the understanding of shareholders for not applying takeover defense measures arbitrarily, its independence from the incumbent management has to be secured. But it does not include a legal requirement for the appointment of independent directors: nor on the way to secure their independence, nor on their number;
- **Third-party share placements** constitute an important legal loophole: the management of listed firms are allowed to place shares or warrants to a third party, thus diluting the holdings of existing shareholders without their consent, whereas this is possible in the EU only after a decision by the shareholders' general assembly;
- **The Bull Dog Court ruling** gave Japan's corporate managers the rationale for implementing defence measures against takeover bids. As the support of the vast majority of shareholders was cited by the Court as a condition of validity for implementing the poison pill, companies have started re-developing **cross-shareholding**, in order to secure broad enough support among shareholders. Accounting rules make cross-shareholding easier as they allow a company not to revaluate its assets until they have lost 50% of their value.

Taxation

European business people consider that taxation is one of the main obstacles which hinders increased foreign investment in Japan. E.g. the high corporate tax rate is considered to be harmful for Japan’s inward FDI but also for Japanese overseas subsidiaries which would like to send profits earnt abroad back to Japan. Greater transparency when enforcing the transfer pricing taxation and the treatment of carrying tax losses in subsidiaries are also mentioned by business as deterrents.

The Cabinet Decision of 27 June 2008(“Basic policies 2008”), which identifies further openness of the Japanese economy to attract FDI as a governmental priority as well as the economic stimulus package of ¥ 11.7 trillion of 29 August 2008 send some signals on taxation reform.

The EU would like to invite the GoJ to inform it about new developments in taxation related issues with impact on companies.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. FDI regulations

a) To ensure that foreign experiences on FDI are duly taken into account when preparing the comprehensive study on FDI regulations called by the" Basic Policies 2008", endorsed by the Cabinet Office of 27 June 2008. In this respect, the EU is ready to share its experience on FDI regulations;

b) To inform the EU of the progress made in the above mentioned comprehensive study of foreign direct investment regulations ;

c) To facilitate foreign ownership of airports ;

d) To ensure that the principles of non discrimination, transparency and proportionality are duly taken into account in the forthcoming review of the Japanese Airport Development Law.

II. Cross border mergers

e) To provide explanations for the lack of success of the current triangular merger scheme and propose measures to make it less cumbersome for foreign investors;

f) To revise accounting standards to limit cross-shareholding.

III. Merger and Acquisition in sensitive sectors

g) To define more clearly the scope and grounds for restrictions on FDI which are felt necessary on the basis of national security or public order concerns and ensure that these restrictions do not have more than necessary restrictive effects on investment;

h) To increase the notification ceiling for investment in sensitive sectors;

IV. Corporate governance

i) For listed companies, to make compulsory the requirements for independent directors (including provisions on number and conditions for independence) in order to ensure that the interests of shareholders are adequately represented;

j) To have third-party share placements authorized by shareholders and not by the management only, in order to avoid shareholders property rights to be diluted without their consent and, in case of a

takeover, to implement the principle that final judgement should be made by shareholders.

V. Taxation related issues

k) 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. in this regard, the EU invites the GoJ to inform it on the monitoring conducted on the application of the tax deferral treatment from the standpoint of legal certainty (see Japanese reply of December 2007);

l) To inform the EU as regards the possible use of the advance inquiry system of the National Tax Agency on tax-deferral for triangular mergers

m) To share with the EU information regarding the options under consideration to expand the range of vehicles available in Japan for mergers, and to extend tax-deferral to them;

n)To inform the EU on new developments on the consolidated tax system reform in Japan, in particular with regard to carrying forward tax losses in subsidiaries, and on the present dividend and royalty payment system between foreign subsidiaries and parent companies which carry out international business;

o) To inform the EU of how transparency is guaranteed in Japan when enforcing transfer-price taxation.

Other relevant dialogue: EU-Japan High Level Trade Dialogue (next meeting on 30 October 2008 in Brussels).

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"On **corporate restructuring**, we heard good news from the Ministry of Finance: the proposed change in the advance inquiry scheme to be implemented in fiscal year 2008 should alleviate EU concerns linked to the tax deferral issue.

As regard **sensitive sectors**, (…) you confirmed that the Japanese Foreign Exchange law abides by international rules; you stressed how, even in areas linked to national security, Japan will observe principles of predictability, transparency and proportionality. We will keep following these developments."

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 current situation continues to be unsatisfactory from the point of view of legal certainty, and has generated considerable costs, confusion and concern.

Case history: first raised in 2005**,** discussed in RRD in 2007. The Japanese reply delivered in December 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 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.

While it may be difficult for an individual company to raise doubts concerning the legality of its own activities in Japan, business associations and chambers of commerce continue to express concerns. 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.

Reform proposals

The EU requests the GoJ to consider the following proposals:

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.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"(…) I had to repeat that, for the sake of legal certainty, the law should be amended, at some point. It is the only way to dispel concerns of headquarters of global companies."

1.3 Human ressources

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. We are observing also developments in relation to the issue of re-entry permit. Concerning admission of personnel with specific skills, sponsorship of domestic staff and driving licences, the situation has seen little change.

Case history: first raised in 2002, discussed in RRD in 2007. The Japanese reply delivered in December 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 that a draft bill for a New Residence Status Control System is currently being prepared for submission to the Ordinary Diet Session of 2009. The EU also welcomes the openness of the Ministry of Justice to exchange information and views on the forthcoming reform. Not all details of the draft bill is known at this stage, but we understand that a simplification of procedures are foreseen. Under the current system, 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 hopes that the revision of the Residence Status Control System will lead to the abolition of the re-entry system or to an equivalent improvement for foreign residents.

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. The EU welcomes the replies made by the GoJ to its 2007 reform proposals and wishes to continue the dialogue on this issue.

S*ponsorship 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. The issue was addressed in the Government of Japan's Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets (December 21, 2007).

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, or provide simplification achieving the equivalent;

b) To allow a broader-range of business executives to sponsor domestic staff; and to give an update of the implementation of the Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets in this regard;

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, including the 10 year experience requirement, 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:

- **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 (also, in view of the possible extention of the resident permit for some categories, from 3 to 5 years, following the new residence status control system);**

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 contributions to defined-contribution pension schemes and allow possibilities for matching contributions and 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.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"As exemplified by the issue of sponsorship of domestic staff, human resources play an eminent role in investment decisions of global companies. **The re-entry permit** remains a concern for foreign residents in Japan. We reiterate our wish to be associated in the review of the re-entry permit.
As regards **securing personnel with specific skills**, we are grateful that MOJ accepted to receive from EU side concrete requests for areas for increased recognition of foreign certificates and licenses (beyond the examples mentioned during the Director's meeting). We will send this list to MOFA and MOJ in the coming weeks.
With the **recognition of driving licenses**, we offered the Police Agency to have discussions and explanations on the way statistical data are collected and prepared in various EU MSs.
On **pension schemes**, we encourage Japan to accelerate the negotiation of bilateral social security agreements with EU Members States."

1.4 Better Regulation, including transparency

Highlights:
Simplifying and improving the regulatory environment, including by increasing transparency in regulations and regulatory enforcement remains a crucial issue. Greater transparency and predictability allow public policy objectives to be met while minimizing costs for business and the economy as whole and disincentives for investment. The EU welcomes the priority given by GoJ to better regulation in some areas of activity. The Financial Services Agency has made better regulation a priority and has taken measures since the announcement of the Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets. There are indications that the dialogue with the industry in this sector has already started to improve. The EU encourages the GoJ to give a greater profile to better regulation in all its areas of activity.

Case history: first raised in 2000 (transparency issue). Better regulation first raised in RRD in 2008. The Japanese reply delivered in December 2007 does not remove all EU concerns.

General comments on Better Regulation
Better Regulation covers policy making from its initial conception to its implementation and enforcement. It relies on transparency, including early public consultation and public access to draft regulation or administrative measure, impact assessment, simplification, codification and repeal of obsolete legislation. While Better Regulation is stated to be a top political priority both in the EU and Japan, its implementing scope and tools remain different. Instead of a horizontal and compulsory approach as in the EU, Japan seems to favours a sectoral approach. The priority given by the Japanese Financial Services Agency (FSA) to Better Regulation illustrates important change in the regulatory cultural environment in Japan.
The EU supports Japan in its efforts to set up a more predictable regulatory environment, including in the enforcement measures, and to stand by the highest international standard of corporate governance.

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.
The EU welcomes that the Ministry of Internal Affairs (MIC) publicised in August 2008 the enforcement status on the public comment procedure for FY2006. It appreciates that a standardised comment period of 30 days is generally applied by Ministries and Agencies (93.8% of the total comment submissions) and that

the FY2006 annual survey mentions the reasons for the length of period for comment submission of less than 30 days.
The EU encourages the MIC to keep monitoring to ensure that sufficient time is secured to take into consideration the comments in establishing administrative orders etc. in line with the ministry's notice in March 2006. Furthermore, the EU considers it important that the GoJ continues to publicise the annual surveys on the enforcement of the public comment procedure, and promote better implementation of the procedure as necessary.

No-Action Letter

The EU welcomes the Cabinet decision of June 2007 that brings improvements to the No-Action Letter (NAL) system[3]: 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. In a case where an inquiry or a response contains information that falls under the category of an event of non-disclosure as prescribed in the Law Concerning the Disclosure of Information Retained by Administrative Agencies, Ministries and Agencies may, as necessary, withhold such information from disclosure. The EU would be grateful to continuously hear from the GoJ the outcome of MIC's comprehensive annual surveys on the implementation of the NAL system by the Ministries and Agencies. In particular, the EU would be grateful to hear an assessment of the first months of implementation of the revised system and, if necessary, what the next steps for improvement could be.

Foreign stakeholders

The EU considers it important that the GoJ ensures that foreign business is given the opportunity to present in due time its valuable experience to regulators, including in the consultations organised or the discussions on impact analysis and assessment, when a new regulation is drafted. Being aware that each advisory council is operated under the Act for establishing Ministry and "The guideline for the operation of advisory councils" of "The basic plan for restructuring and rationalisation of advisory councils" (the Cabinet decision on 27th April 1999), the EU does not consider that in Japan, foreign business organisations, in a general manner, are given sufficient access to advisory councils (*shingikai*), study groups *(kento kaigi)* and similar consultative organs during the consultative process leading to possible new legislation. From the bitter experience on the Article 821 of the Corporate Law, the EU asks the GoJ to adopt and implement a horizontal policy, not on a Ministry-to-Ministry basis, more favourable to the involvement of foreign business organisations in the consultative process of decision making.

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

The EU would like to raise the two following cases for consideration by Japan in the light of the principles of transparency and non discrimination.

(i) The Japanese Ministry of Justice (MoJ) and Japan's bar association have set up in June 2008 a Foreign Lawyer System Study Group to consider the issue of foreign lawyers' activity in Japan. The EU understands that the focus of the study Group is the availability of branching and the use of the bengoshi hojin.[4] The EU is concerned to learn that MoJ did not ask the groups who have been active in leading discussions with MoJ on these issues and who may be representative of interested parties, including for instance the European Business Council (the "EBC"), to provide members of the Study Group. The EU is also disappointed to learn that no foreign lawyers have been designated as full members of the Study Group. Moreover, none of the Japanese lawyers named to the Study Group is in a Japanese firm which has full foreign partners. The selection of observers has not been representative of those who might be interested in the process.

(ii) The useful government-private sector consultations in 2007 which preceded the Customs Law amendments in April 2008 and the expansion of the Authorized Economic Operator (AEO) program were not continued during the subsequent drafting of the implementing regulations. Ongoing consultations will be more and more needed as the intricacies of implementing the AEO programme become more evident to the Government and domestic and foreign private sector.

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 positive developments following the coming into force of the revised GPEA on October 1st 2007. The EU welcomes the August 2007 guidelines issued by the MIC 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. The EU also welcomes that the MIC publicised the FY2007 annual report on the policy evaluation in June 2008 as well as the status of the trial implementation of the RIA in October 2007.

While appreciating efforts of Ministries and Agencies to enhance the quality of policy evaluation as shown in the annual report, the EU reiterates its request

[4] Foreign law firms, or joint companies between foreign and Japanese lawyers, are not allowed to set up a *bengoshi hōjin*. As, currently, only *bengoshi hōjin* (corporate legal personality for a law firm) are allowed to set up a branch, foreign law firms can not have more than one office in Japan.

that the GoJ extends the compulsory application of ex-ante evaluation of regulations to all fields of activities. It is important that the results on ex-ante evaluation of regulations should be made public and be subject to public opinions.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. <u>With regard to Better Regulation</u>

a) To pursue its efforts to set up a more predictable regulatory environment, including in the enforcement measures, and stand by the highest international standard of corporate governance.

b) To continue to exchange experience on the implementation of Better Regulation.

II. <u>With regard to the implementation of the Japanese Public Comment Procedure</u>

c) To promote better implementation of the public comment procedure, as necessary;

d) To continue to publish the annual report to assess how far the Public Comment Procedure has been implemented by ministries and agencies;

III. <u>With regard to the No-Action Letter</u>

e) to hear from the GoJ the assessment of the first months of implementation of the revised system in order to see the effectiveness of the NAL system for the European stakeholders, and to hear how the system could be further improved.

IV. <u>With regard to the participation of European-affiliated stakeholders in the decision-making process</u>

f) To ensure that foreign business is given the opportunity to present in due time its experience, when a new regulation is drafted;

g) To adopt a 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.

h) To ensure that the Study Group on Foreign Lawyers will give the opportunity for foreign lawyers to present their views and experience on the issues discussed by the study group and give due consideration to the concerns of foreign lawyers;

i) Ministry of Finance (MoF) (including the Customs & Tariff Bureau) and the Ministry of Land, Infrastructure & Transport (MLIT) to establish formal government-private sector consultations on implementing regulations for the AEO Programme, in view of their operational impact.

IV. With regard to the use of Regulatory Impact Analysis

j) To extend the compulsory application of ex-ante evaluation of regulations to all fields of activities;

k) To take into account public input while processing ex-ante evaluation of regulations, not only in the cases where a public comment procedure is carried out.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"Beyond the good news from the Ministry of Finance, we will follow how different Ministries will implement the June 2007 revised Cabinet Decision on No Action Letter, especially as regard requests of confidentiality by inquirers.
Other issues of interest are well known:
- allow sufficient time for consultation in public comment procedures;
- adopt a horizontal policy, not on a Ministry to Ministry basis, for involvement of foreign stakeholders
- extend the use of Regulatory Impact Assessments to all fields of activities."

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 with a view to achieving increased liberalisation and expansion of government procurement markets. The EU attaches great importance to strengthen cooperation with Japan in the area of e-procurement.
Further progress is necessary on issues such as bid-rigging, Japanese law translation, the expansion of the Comprehensive Evaluation Method. European business people still consider that, in spite of the opportunities offered by Japan's membership to the GPA, in many instances it is easier to deal with the Japanese private sector than with the Japanese public sector (e.g. access to railway procurement, single point of public procurement information, administrative obstacles).

The issues of Japanese public works thresholds and of access to the public procurement of local Authorities (cities/*shi-*, towns/*machi-* and villages/*mura)*, which are of utmost importance for European companies, will be addressed bilaterally with Japan in the margins of GPA negotiations.

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

Cooperation in the area of electronic procurement

As e-procurement develops worldwide, legal and technical choices in e-procurement systems may create technical barriers that risk reducing business opportunities for Japanese and EU businesses in respectively the EU and Japan.

The EU notes with much interest that a working group of the Nippon Keidanren "Committee on e-Government" and the "e-Government Evaluation Committee" of the GOJ have expressed their wish to visit the European Commission in October as part of their study tour to understand the EU legal system in the area of e-government.

The EU also notes that Japan has adopted the Law on the Use of Information Technology in Administrative Procedures, the Law Concerning Electronic Signatures and Certification Services and the Legal Provisions Relating to Electronic Signatures and Certification.

The EU would therefore welcome the possibility to pursue the cooperation with Japan in the field of e-procurement, at expert level, notably by exchanging information (e.g. by offering Japanese experts the opportunity to participate as

observers in the meetings of the Working Group on electronic public procurement of the Advisory Committee on Public Contracts).

Opening in practice the access to railway procurement

Access of foreign firms to the public procurement of rolling stock in Japan by railway and urban transport operators is extremely narrow. According to the JARI – Japanese Association of Rolling Stock Industries – the total sales of rolling stock in Japan have reached on average 374 billion JPY every year, or some 2 billion EUR. In 2005, only 5.2 billion JPY/33 million EUR of all rolling stock sales were covered by open procurement procedures under the terms of the GPA, of which foreign firms only obtained 15%. This implies that only 0.25% of the Japanese market was eventually awarded to non-Japanese firms.

This situation is surprising, given that the EU railway supply industry amounts to 60% of world production and that the Japanese represents only 10%.
The EU believes that this situation is due to the extensive use of the Note 4 of Japan's appendix to the GPA which allows Japan to exclude procurement awarded in the telecom or railways sector for "operational safety" reasons. The EU is of the opinion that excessive use is being made of this provision, leading to a regrettable imbalance which deserves the consideration of reciprocity clauses.

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

The EU would also welcome from Japan additional transparency in the implementation of this provision, whose conditions of use should be made transparent, proportionate and predictable. In these conditions, the EU would appreciate obtaining from Japan further clarification as to the interpretation of both the legal and technical conditions that allow Japanese contracting Authorities to invoke its application.

Single point of access for public procurement business opportunities

The EU notes that a single point of access in Japan equivalent to EU's own electronic centralised tender database "TED" is lacking. The EU considers that such a system can make a positive contribution to the transparency and efficiency of public procurement markets, thereby allowing public funds to be used more efficiently. 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 would also welcome notices published in this centralised website being

made available in English or any WTO language. This would enhance the access to local procurement which is not accessible in the JETRO website.

TED provides an instant overview of all tenders launched - or to be launched - for any member of the public in any of the EU's Member States and covers all levels of government (central sub central, utilities, etc). It also gives the possibility to businesses to monitor calls for tender for their types of products, works and services thanks to the CPV (available in 22 languages).

A more coordinated legal framework

The Japanese legal framework for public procurement 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 covered 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.

The EU would like nevertheless to thank Japan for the efforts it has undertaken to translate its legislation into English. It would like to know from the Japanese Government if it has a specific calendar for further translation and codification of relevant legislation.

Removing administrative obstacles that EU firms face in Japanese public procurement.

(a) Business evaluation (keishin)

The EU continues to consider that business evaluation poses two main problems:

1. The process is too long to allow companies to participate adequately in a particular tender after publication of a tender notice (cf. Article XI of the GPA provides for a minimum 40 days time-limit for the receipt of tenders from the date of publication of a tender notice).
2. 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 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.

(b) Compulsory registration before each procuring entity

Japan has started to improve the system of compulsory company registration at central level. The EU welcomes such a move and believes it should be extended to the local level as this requirement places a disproportionate burden on suppliers. Companies – which also undergo the keishin/business evaluation in parallel- are obliged to register with each procuring entity. Registration is required every two years and there is no automatic renewal. This is in contradiction with an efficient tendering system, especially where parallel administrative procedures require bidders to submit overlapping sets of information.

Open and Selective Tendering

The EU continues to be concerned with the extensive use in Japan of Selective tendering procedures, not to mention Limited Tendering procedures. Moreover, as no interested supplier is eligible to submit a tender without having been examined first regarding his qualifications in one way or another, the EU continues to have difficulties to understand the real difference between an "open and competitive procedure" as applied in Japan and selective tendering.

In the EU, the use of open tendering compared to selective or limited tendering has been growing over the years. In 1995, only 52% of procurements followed an open tendering, whereas 30% of procurements followed a selective tendering. In 2007, this number has reached 77% for open tendering and 12% for selective tendering.

Towards "better value-for-money" and more" innovation" in tendering

The EU would welcome a more innovative approach to procurement, which is less narrowly focused on price and where procuring entities look at value-for-money and actually avail themselves of the full diversity of technical solutions available on the market. This also corresponds to the reality of highly-developed economies like Japan and the EU, where "differentiation" and "added value" are at the heart of companies strategies.

(a) Less focus on price, more focus on quality and innovation

The EU welcomes the objectives set by the GOJ for the use of the "Comprehensive Evaluation Method" in public works, both at Central and Local level. This radical change in the way of awarding contracts in Japan should, if that is not the case already, be extended to the public procurement of services and supplies. In particular, EMAT (economically most advantageous tenders) allows for the procurement of innovative materials, designs and techniques, which appear to be more marketable to Japanese private companies than to the Japanese public sector. In the EU, for instance, EMAT accounts for 72% of all

procurements (price-only accounts thus for only 28%), whereas it accounts for 67% and 77% of supplies and service procurement respectively.

(b) Towards broader technical specifications

Reports suggest that in Japan 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. As a result, 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. 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.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. <u>Cooperation in the area of electronic public procurement</u>

a) To exchange regularly information on legal and technical choices in e-procurement, in particular through the participation of Japanese e-procurement experts to the meetings of the Working Group electronic public procurement of the Advisory Committee on Public Contracts

II. <u>Opening in practice railway procurement</u>

b) To end the "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 Annex 3 to the GPA;

c) If the "operational safety exceptions" cannot be ended, their use should be made <u>transparent</u>, <u>proportionate</u> and <u>predictable</u>.

d) To provide in the mean time comprehensive explanations on the interpretation of the legal and technical conditions under which the "operational safety clause" is invoked;

III. <u>Single point of access for public procurement business opportunities</u>

e) To set up a free of charge electronic single point of access where *all* Japanese tender notices (central, local, etc) are published and available in English (at least a summary), as it is an essential way to enhance the competitive elements of the procuring process.

IV. A simpler legal framework

f) 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;

g) To make available all applicable public procurement legislation both at central and local level in English;

V. Remove administrative obstacles that EU firms face in Japanese public procurement

h) To eliminate the obligation for companies to undergo the business evaluation prior to tendering. If 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.

i) 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.

VI. Open and selective tendering

j) 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

k) To actively encourage the use of open tendering procedures in comparison to selective or limited tendering procedures

VII. Towards more "better value for money" and more" innovation" in tendering

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), in particular for services and supplies. 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);

m) 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".

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"We are grateful for the fruitful exchange that took place yesterday during experts meeting. On the EU side, serious concerns have been raised on the lack of transparency and predictability of the Japanese procurement framework. Furthermore there is a strong feeling of unbalances in terms of respective access to procurement market. I hope we can work to find mutually acceptable solutions, including in the framework of the ongoing WTO negotiations in the GPA (Government Procurement Agreement).

Lastly, let me recall our proposal to enhance bilateral cooperation on procurement conducted electronically during the forthcoming year in order to report adequately to the next RRD meeting in Tokyo."

3 – Information and communications technology (ICT)

3.1 Strengthening the competitive safeguards to guarantee transparent, non-discriminatory and cost oriented access to bottleneck facilities and interconnection, especially in the context of the development of next generation networks.

Highlights:
As recalled in previous years, to guarantee a fair level of competition in the electronic communications markets, 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 a constant effort to ensure maximum transparency in the costs of the incumbent operator and the terms/conditions applied to its subsidiaries for those services.

The development of Next Generation Networks (NGN) is a positive trend but requires attention to guarantee the above principles and to address new important challenges.

Case history: recurrent issues, discussed in 2007

Background:

As recalled in previous years, to guarantee a fair level of competition in the electronic communications markets, 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 a constant effort to ensure maximum transparency in the costs of the incumbent operator and the terms/conditions applied to its subsidiaries for those services.

In 2007 RRD, the Government of Japan (GOJ) underlined the measures taken to ensure that incumbent operators provide interconnection to competitive operators in accordance with the principles of transparency and non-discrimination, especially article 33 of the Japanese Telecommunications Business Law. Reference was also made to its ambitious "New Competition Promotion Program 2010" that should address changes in the market environment caused by the progress of broadband and the transition to IP-based networks. Within this framework, work in areas such as the interconnection rules applicable to next generation access networks of the NTT EAST/WEST has continued.

The development of Next Generation Networks (NGN) is indeed a positive trend but requires attention to guarantee the above principles and to address new important challenges.

The European Commission has launched a public consultation (open until 14th November 2008) on a future Commission Recommendation on Regulated Access to Next Generation Access Networks (NGA Recommendation). This document, to be finalized and adopted in 2009, addresses important issues such as access conditions, rates of return and appropriate risk premiums.

Transparency

In general terms, in the case of vertically integrated undertakings such as NTT EAST/WEST, it is essential that the principle of non-discrimination is duly implemented, in particular when services are supplied to companies with whom they compete on downstream markets. In this case, it would be advisable that systems via which competitors order those services are equivalent to those used by the incumbent's own retail operation and to ensure that customer information from competitors is kept confidential and not passed to other parts of the incumbent.

Interconnection charges must reflect costs which should be justified by detailed information on the cost structure of incumbent carriers. In this situation, the imposition of proper accounting separation is especially useful to allow internal price transfers to be rendered visible and to check compliance with non-discrimination obligations. In order to avoid unfair cross-subsidy, NTT EAST/WEST should keep transparent and publicly available separate accounts to identify interconnection activities from other activities.

This is also largely applicable to charges imposed on operators for the financing of universal service obligation. Such charges must be equally justified on the basis of detailed information on the costs of the beneficiary.

More specifically, in order to allow all operators to have the opportunity to compete on an equal footing in the new environment created by the development of NGNs, transparency will be even more essential. Before any large scale investment takes place, it is essential that reference unbundling offers are adjusted (taking account of the changes foreseen) and publicized. These offers should be complete, timely and accompanied by service level commitments. The regulator should also specify the procedures and the timing whereby NTT EAST/WEST has to provide information to interested parties about changes in its access network architecture to the extent necessary for the planning and coordination of investments. Finally, it is important that the regulator foresees a mechanism that allows him to follow the negotiations and intervene rapidly, in particular where dominant operators are delaying access to competitors.

Prices

In the absence of a commercial or negotiated agreement with respect to access to inputs or wholesale services, the regulator should set the terms on which NTT EAST/WEST will grant access to a third party. This raises the issue of the prices on the basis of which access is mandated. Prices must preserve incentives to invest and innovate while allowing a fair access and preserving competition. The return on investment to finance NGN should provide adequate incentives for companies to invest, promote efficiency and sustainable competition and maximize consumer benefits. In order to achieve this balance, the draft Commission Recommendation on Regulated Access to Next Generation Access Networks proposes to compensate companies for the relevant risks (i.e. project-based and non diversified risks) that they face, when making the investment. It also proposes to base the return allowed on equity capital on a concrete pricing model (this model should be based on realistic assumptions and rigorous implementation through an objectively verifiable methodology). The Capital Asset Pricing Model (CAPM), the most widely used methodology for calculating the cost of equity in regulatory pricing models, is considered to be an adequate instrument to calibrate such required rate of return. This been said, other methods could be used if they are fully justified as meeting the same quality standards.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To ensure that regulation guarantees that incumbent operators provide interconnection according to the principles of transparency, non-discrimination and cost orientation, and appropriate measures are taken to verify compliance with these principles (e.g. accounting separation, availability of detailed cost information);

b) To give assurance that these guarantees are adequately implemented regarding access to next generation networks;

c) To ensure that business sensitive information provided by competitors to vertically integrated incumbents, in the context of interconnection/access requests, is used only for the purpose of implementing such a request.

Other relevant dialogue: The EU-Japan Information Society Dialogue (the latest meeting was held in Tokyo in March 2008).

3.2 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 the initiatives undertaken in by the GoJ to reform its mobile telecommunication equipment market. In particular, the EU is concern about the negative effects that the system of "blanket licensing" could have on the access to the market of wireless communications terminals not distributed by mobile operators.

Case history: Conformity assessment issues were discussed in RRD in 2005. Blanket licensing and network neutrality were first raised and discussed in RRD in 2007.

Conformity assessment procedure

The EU acknowledged already 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 R&TTE directive (Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, OJ L 91, 7.4.1999), without any additional requirements, for any EU telecom equipment import.

Blanket licensing

The system of "blanket licensing" for mobile telephony terminals is an additional matter of specific concern. In the EU telecommunication operators are under the obligation to connect all radio equipment that complies with the R&TTE Directive. This initiative contributed to avoid the control of the terminal market by operators and to make it more competitive, increasing substantially the amount of terminals marketed outside the control of operators.

Blanket licensing does not benefit the Japanese consumer. In a mobile market with a limited number of market players and that bundles/subsidizes handsets, the control of these operators over the terminal market could seriously hamper competition and innovation. Handsets integrating capabilities that would conflict with operators' business strategies will have difficulties to reach the Japanese market:e.g. terminals that could use competing networks such as WiFi or

competing applications. As a result such terminals are largely relegated to the upper end of the market and competition in the mobile market in Japan is limited.

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 mobile operator practises (bundled offers, handset subsidies and practices reinforcing the control of mobile operators on the terminal market) 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) Equipment with SDoCs issued by European producers should not be subject to additional requirements, such as an specific license for the use of radio spectrum;

c) To extend the scope to SVC to wireless radio equipment;

d) To start exchange of views with the EU on issues such as the impact of blanket licensing and of mobile operator practises (bundled offers, handset subsidies and other practices reinforcing the control of mobile operators on the terminal market) on market access for mobile terminal equipment.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"We take note of the good cooperation between EU and Japan experts on ICT, in particular on the issue of interconnection (item 3-1), on universal service financing (item 3-2), on spectrum for IMT-advanced (item 3-3) and on blanket licensing. Some of these issues will be addressed in the next bilateral ICT dialogue on 4th March 2008. Report on the follow up will be done in the next RRD meeting in Tokyo

However, we regret that Japan can not make progress on EU concerns related to the telecom equipment (issues related to the acceptation by Japan of the European supplier declaration of conformity, and to the extension of the scope of the implementation of the Japanese self verifications of conformity to wireless radio equipment).

Further discussion at expert level will be held next year and report will be made at the next RRD meeting in Tokyo."

4 – Financial services

Highlights:
The EU welcomes the wide-ranging changes to the Financial Instruments and Exchange Law (FIEL) to reinvigorate the Tokyo market, which were passed by the Japanese Diet on 2008 June 6. They are the first legislative step in implementing the Government of Japan's Better Market Initiative (Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets, December 21, 2007).

This step addresses some of the EU RRD main concerns, i.e. better regulation and firewalls. But actual implementation will determine whether or not the ambitious objectives will materialize into gains for the Tokyo market, the financial services industry in Japan and Japanese citizens.

Universal banking should remain the long-term goal of the GoJ. It reflects a global trend: with IFRS being progressively accepted as the accounting standard reference, with systemic risk watched at global level, regulations of financial institutions will have a tendency to converge.

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

4.1 Banking and investment services

Soundness of the international financial system

The EU welcomes the announcement that FSA will expand networks involving information exchange between the European and Japanese supervisory Authorities and multilaterally in order to ensure international consistency of regulation and supervision. To improve the soundness of the financial system public Authorities should take measures to help the market better deal with information related to risk, especially for securitised products. Following the conclusions of the February 2008 G7 finance ministers in Tokyo, the EU welcomes the work carried out by the GoJ at the Financial Stability Forum (FSF), including at the high-level working group set up to work out policy recommendations aimed at enhancing market and institutional resilience. All countries, including Japan, should now implement quickly the FSF recommendations allowing for a coordinated response to the current financial turmoil.

Better Regulation

The EU welcomes the priority given by the FSA to Better Regulation, in particular reflected by FSA's first progress report published on 2008 May 19 and by the agreement reached on 2008 April with Industry to publish 14 key principles to govern the financial services industry. In this regard, the EU welcomes the active involvement of the industry in the preparation of these principles; consultation with industry will be very important to further define their scope. This is a major step forward in promoting a principle based supervisory approach in Japan.

An important issue remains the industry's need for transparency and consistency in the implementation of the regulatory framework.
The EU encourages FSA to pursue its approach on Better Regulation. However, it should be noticed that a tool like the "No Action Letter" does not yet provide a satisfactory answer as it is too cumbersome. Codes of conduct and clear rules of enforcement can provide transparency. In this regard, the EU welcomes the publication by the FSA of its basic policy in terms of inspections and hopes that it will contribute to streamline the inspection process.

Elimination of firewalls

Until now, Article 33 of the Financial Instruments and Exchange Law imposes a ban on the concurrent operations of banking and securities activities. Regularly, the EU has highlighted the negative impact of Article 33 on the Japanese economy, in particular with regard to the goal of making Tokyo an international financial centre. In particular, customers in Japan can not benefit from the full range of services; innovation is hindered, international companies are in practice encouraged to conduct business outside Japan.

Thus, the EU welcomes the decision to revamp the firewall regulation by 12 June 2009. However, it strongly encourages Japan to adopt appropriate implementing measures to ensure the full potential of this measure will be realised. In this regard, the limited impact of the measures taken to relax some of the firewalls should be duly remembered (e.g. 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).

On the three above mentioned important areas, the EU would like to share its experience by submitting detailed proposals on the way to implement the changes envisaged by GoJ:

* *On easing the restrictions on customer information sharing:* as regards corporate information, the EU is pleased that the opt-in system was changed to opt-out last June. Even if a corporate client opts out, the EU considers it important that the new rules should provide for the right to

share information for "internal control purposes" without FSA approval. The EU believes this important measure should not be watered down by the way the opt-out procedure will be implemented. Offering companies to opt out for a limited time or allowing them to opt out at any time, even over several years, would certainly not have the same impact that can be expected from the amendment to the FIEL on the financial services industry in Japan. Obviously, for this measure to be fully effective, the opt-out should be limited in time. In the same vein, the interpretation of "internal control purposes" should be broadly defined.

* *On the abolition of the ban on concurrent working position among securities firms, banks and insurance firms:* the GoJ should not only authorise financial services firms to appoint a country manager who can oversee all Japan operations and make managerial decisions based on group-wide information, but it should also consider permitting cross-marketing of products by double hat officers and employees, as it is the case in the EU.

* *On the prevention of conflicts of interest:* the EU strongly recommends the GoJ to adopt a principle based approach, that is to say to avoid prescribing in details the way to control conflicts of interest in the revision of the FIEL and related ordinances. Regulations should not go beyond the requirement to establish an internal system and policies to prevent conflict of interest at each firm, allowing for a flexible response by financial institutions. The detailed criteria, modalities and application should be left to the best practices of the financial industries, as it is the case in Europe.

Liberalisation of trust banking

The EU regrets that no progress was made on 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 the definition of authorized banks which can engage in trust banking. In the EU, concurrent operation of banking and trust business is possible in those countries of the EU where trust business is practised. We reiterate our openness to receive from the FSA a note or a non-paper on the prudential analysis of the trust-banking sector in Japan.

Full consolidation of rules and regulations governing the asset management industry

The EU welcomes the consolidation, under the FIEL, of the regulations related to investment trust management firms and investment advisory firms. This leads to a single registration system as a Financial Instrument Firm providing

investment management services and to supervision of the two sectors by the Asset Management Office of the FSA. Moreover, the EU also welcomes the decision of June 2008 of the Japan Investment Trust Association and the Japan Securities Investment Advisers Association to set up a working group to examine the modalities on their merger.

The EU notes that the Japan Investment Trust Association has become a self-regulatory body since September 2007, under Article 78 of the FIEL. The EU considers that the Association should be autonomous and play its self-regulatory roles, including inspection of its member firms, without duplicating the supervision carried out by the FSA.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To implement, in an internationally coordinated way, the recommendations of the Financial Stability Forum (FSF) as a response to the financial turmoil;

b) To implement on a larger scale its policy of Better Regulation in the financial services area, that is to say to promote principle-based regulations and ensure that the financial industry applies the rules;

c) To share experience with the EU on progress of implementing the Better Regulation approach in the financial services;

d) In the context of the elimination of firewalls envisaged, to implement the opt-out system in a way that will actually ease the restrictions on customer information sharing;

e) To authorise financial services firms to appoint a country manager and to carry out cross-marketing of products;

f) As regards prevention of conflicts of interest, to leave detailed criteria, modalities and application to the best practices of the financial industries, as it is the case in Europe. The EU is open to share its experience with Japan in this regard;

g) To ensure that discrimination between foreign and domestic bank branches interested in engaging in trust and banking business concurrently be suppressed at short notice. In this regard, Article 1 of the Law concerning Concurrent Management of Trust Business by Financial Institutions should be revised;

h) To encourage the Japan Investment Trust Association and the Japan Securities Investment Advisers Association to merge as soon as possible;

i) To ensure that the revamp of the firewall regulation is also applied to investment advisors;

j) To avoid duplication of regulatory roles played by the Japan Investment Trust Association and by the FSA;

k) To keep universal banking as a governmental priority.

Other relevant dialogue: High-Level Meeting on Financial issues between the European Commission and FSA (Next meeting to be held on 1 December 2008 in Brussels).

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"(…) we are pleased to see that a good deal of progress has taken place. This is very much linked to the debate on how to restore Tokyo as a major financial centre but we should acknowledge this progress in the framework of our Regulatory Reform Dialogue."

4.2 Insurance

Highlights:
The EU reiterates its requests that the GoJ suppresses without delay the remaining restrictions applied to the sale of insurance products by banks and eliminates the differing treatment applied to regulated *Kyosai*

The EU supports GoJ's work on solvency reform in line with developments in the IAIS and methods being developed in the EU (Solvency II).

Case history: first raised in 1999, discussed in RRD in 2007. The Japanese reply delivered in December 2007 does not remove all EU concerns. The proposal of a EU-Japan insurance dialogue is first raised in RRD in 2008.

Deregulation plan for the sale of insurance products by banks

Despite the positive step of the deregulation of bancassurance activities allowing banks to sell all insurance products since 22 December 2007, extra restrictions seem to apply to bank sales relative to other channels (e.g. restriction on sales of insurance products to SMEs by a bank which extends loans to a small firm). The EU notes that GoJ did not consider the EU 2007 RRD proposal that no conditions should be attached to the sale of insurance products through bank networks that would reduce the impact of liberalisation. The EU considers it important that the GoJ starts an early review of these extra restrictions ahead of the 3 year review currently promised. Whilst sales are picking up slowly, there is yet to be a level playing field, and this is not in the interest of Japanese consumers.

Consumption tax is charged on commission on the sale of insurance products

Consumption tax is charged on commission fees on the sale of insurance products through third party agents. However it does not apply to commissions (salaries) paid to internal agents, thus creating inconsistency and discrimination in the treatment of the different distribution channels. As foreign players and new entrants tend to choose independent agents for their distribution, there is a lack of level playing field to the detriment of new entrants and of foreign companies. Moreover, as financial products are exempt from consumption tax, this practice does not seem to be in line with the OECD's February 2006 "International VAT/GST Guidelines" that state that "In principle, business should not bear the burden of the tax itself since there are mechanisms in place that allow for a refund of the tax levied on intermediate transactions between firms". In the EU, the sale of insurance products through an independent insurance broker is exempted under the VAT Directive.

Cooperation on solvency calculations

Enhancing the regulatory environment for the insurance industry is critical to future development of this sector. It is important that the Japanese solvency calculation methodologies foster product innovation and be a reliable indicator for insurers' relative financial health.
The EU very much welcomes the exchange of views over the past months in the frame of the IAIS committees and sub-committees as well as bilateral exchanges on the Solvency II Directive proposal and would like to continue and deepen these exchanges. In this regard, the EU sees good prospects and is ready to start with Japan an EU-Japan Insurance dialogue in 2009, which would include the Japanese FSA, the Committee of European insurance and occupational pension supervisors (CEIOPS) and the European Commission. Such a dialogue, to be set up under the umbrella of the already existing bilateral dialogue on financial services (EU-Japan High Level Meeting on Financial Issues), would help to underpin the development of new international solvency standards that will promote effective risk management and international convergence. A specific EU-Japan Insurance dialogue would also provide a natural forum for discussions on topics such as possible equivalence of solvency requirements between Japan and the EU as well as the IAIS Guidance Paper on the Mutual Recognition of Reinsurance Supervision.

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 PPC 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, moving to a post-funded scheme, as in other developed insurance markets, would enhance the efficiency of the insurance industry and

remove the moral hazard. Contributions to PPC's financial resources should be a function of the risk of the product. The EU would like to invite the GoJ to share with the EU its present thinking regarding the PPC scheme and prospects, including the treatment of variable annuity products.

Regulated Kyosai

In the replies to the EU 2007 RRD proposals, the GoJ described Kyosai as "mutual aid associations composed of members circumscribed by region or workplace" whose "activities are of a different nature than the profit-making insurance businesses that target the general public".
It should be noted that one year later, regulated *Kyosai* have aggressively expanded their product ranges and increased their efforts to expand membership. For instance, the agricultural *Kyosai* expanded its benefit coverage in April 2007 for existing medical and nursing care insurance products and introduced a new medical care insurance product for seniors. According to the most recent available data by Japan Cooperative Insurance Association, *Kyosai* regulated by Ministries other than FSA sold nearly 25% of all life insurance policies and accounted for 30% of all insurance premiums for non-life insurance policies in Japan.
Having millions of customers, these so-called "regulated" *Kyosai* directly compete on the market as large-scale insurance companies. In such a context, the EU would like to reiterate its request that a level playing field should be established before any business expansion.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To review the extra restrictions which apply to bank sales relative to other channels;

b) To ensure consistency and level playing field in the treatment of the different distribution channels when it comes to consumption tax on commissions on the sale of insurance products, taking into account the OECD guidelines;

c) To set up a specific EU-Japan Insurance Dialogue, under the EU-Japan High Level Meeting on financial services, which would address, inter alia, the issues of insurance and reinsurance solvency regulations in Japan and in the EU;

d) To ensure that companies which contribute to the PPC scheme are involved in the PPC review;

e) To share with the EU its current thinking on the PPC scheme and its prospects;

f) To move to a post-funded PPC scheme;

g) To end the favoured status of Kyosai, 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 (Next meeting to be held on 1 December 2008 in Brussels).

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"In particular, I would like to mention the revision of firewalls and the full deregulation of bancassurance activities. These are major steps towards universal banking. (…) However, we regret that there are a few remaining points where there is no progress at all, such as the issue of trust banking or the issue of "regulated" kyosai."

4.3 Auditing

Highlights:
The EU and Japan are involved in a cooperative process to reach the goals of moving towards mutual reliance on each others' regulatory systems, as well as enhancing mutual understanding, co-operation, and exchange of information in the area of auditing. DG MARKT maintains good and constructive relations with JFSA personnel.

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

Background

In the context of the ongoing work on the recognition of equivalence of the FSA and the Certified Public Accountants and Auditing Oversight Board (CPAAOB) under Art 46, the JFSA has agreed to cooperate. The Commission has decided in August 2008 to grant Japanese audit firms with a transitional period until July 2010, which eases the timeframe for the process of assessing a possible equivalence of the JFSA/CPAAOB under Art. 46. Next step should be a first round of information request from the Commission to the JFSA in November 2008. Accordingly, the EU has put in place a policy and a legal framework allowing relying on inspections in Japan. The US (the PCAOB) has also suggested a framework on how to rely in full on inspections carried out by non US authorities though it did not yet finalise it. A major issue is however that Japan has neither introduced nor proposed regulatory measures or a guidance on how they intend co-operating and relying on non Japanese authorities.

Building the context in which information exchange between the JFSA and EU oversight bodies would be possible under Art. 47, the JFSA was responsive to

the EU requests for information in 2008, It also expressed interest in entering into such an information exchange scheme, possibly on the basis of Memorandum of Understanding between the JFSA and EU audit regulators. The Commission intends tabling a Decision before the end of 2008 regarding Art. 47, and is currently considering whether the Japanese Authorities could be considered competent under Art 47. Therefore, continuous dialogue and exchange of information are necessary.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) In the frame of the transitional regime granted to Japanese audit firms until July 2010, to ensure that the JFSA/CPAAOB assist the relevant Japanese audit firms providing relevant information (including inspection reports as appropriate) to the relevant EU audit oversight bodies;

b) To develop appropriate legislative or regulatory framework with a view to create an effective regime for EU audit firms registered with the JFSA so that the JFSA would accept inspections are carried out by European oversight bodies and that there is no need for inspections by the JFSA/CPAAOB;

c) To ensure, in the frame of Art 47, that a continuous and constructive dialogue continues to take place between DG MARKT and the JFSA/CPAAOB.

Other relevant dialogue: Bilateral dialogue on auditing between the European Commission and FSA set up in November 2006.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"(…) we have established a close cooperation with the FSA through the Monitoring Meetings, and we hope this good cooperation will continue in the future with the aim to achieve equivalence in the auditing field."

4.4 Accounting

Highlights:
The EU strongly supports the efforts of the Japanese Authorities and the Japanese Accounting standard Board of Japan (ASBJ) in setting up and adopting a time-framed programme to achieve convergence with IFRS. The Tokyo Agreement of August 2007 with the International Accounting Standard Board (IASB) is a key element in accelerating the implementation of this regulatory convergence programme. The EU strongly encourages Japan to

pursue the convergence process as foreseen in the Tokyo Agreement and to consider moving to IFRS as soon as possible.

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

Accounting convergence

Based on the EC Regulation 1787/2006 and the Commission Decision 2006/891/EC, third country issuers are exempt from the obligation to use EU IFRS or to restate financial information in accordance with EU IFRS until the end of 2008. As of 2009 a new legal measure (equivalence decision) will be in place.

In July 2007 and in April 2008, the European Commission provided a first and second 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).

Based on the definition of equivalence and the equivalence mechanism adopted in December 2007, the Commission will adopt a new legal measure with effect of January 2009 regarding the granting of equivalence or a transitory regime. The Commission consults the Committee of European Securities Regulators (CESR) on these proposals.

On 11 June 2008 the Commission published a proposal regarding third country GAAPs in the EU as from 2009. In this proposal, the Commission concluded that as of 2009 Japanese GAAP should be considered as equivalent to IFRS, which would allow Japanese companies listed in the EU to continue the use of Japanese GAAP. The proposal is currently under discussion at the Council and the European Parliament and a final equivalence decision is expected for October 2008.

The EU encourages Japan to continue its efforts toward convergence in order to establish a permanent process to eliminate all existing differences between Japanese GAAPs and IFRS.

Adoption of IFRS

Recently, Nippon Keidanren and the Japanese Institute of Certified Public Accountants have expressed their support for the use of IFRS in Japan. The EU notes that there is strong momentum in Japan on the issue of adopting IFRS, following the US Securities and Exchange Commission roadmap of August 2008, which will allow, from next year on, the use of IFRS for a limited number of domestic companies.

The EU understands that, after discussions with relevant parties, the Japanese FSA will have to make a formal decision on this question by the end of the year, and that work would then start in the framework of FSA Business Accounting Council to discuss a roadmap, schedule and time line towards the possible adoption of IFRS. In this context, the EU encourages Japan to consider moving to a direct adoption of IFRS, instead of adapting Japanese GAAPs to IFRS, as soon as possible.

IASB governance

The EU considers it important to maintain the close cooperation between the EU and Japan, together with the US, on strengthening IASB governance. Indeed, strengthening IASB governance has become a top priority these days, even more with the issue of fair value being at the centre of the debate on the follow up to the current financial crisis.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To ensure that the process of convergence between Japanese GAAPs and IFRS is ongoing and the momentum and support within Japan are kept at the highest possible level even beyond the year 2011;

b) To ensure that the established regular dialogues with key partners in the EU (EU-Japan Accounting Monitoring Sessions; bilateral contacts with the European Financial Reporting Advisory Group - EFRAG) on the one hand, and with the IASB on the other hand, are maintained in the accounting field;

c) To ensure that the standard setting expertise and resources in Japan are efficiently used to provide strong and timely technical input into the IASB standard setting process;

d) To consider taking a formal decision to adopt IFRS and start concrete work in this respect, including the design of a roadmap on the way towards IFRS;

e) To continue to cooperate closely with the EU on the issue of strengthening IASB governance.

Other relevant dialogue: Monitoring sessions on convergence between the EU Commission and the Japanese FSAI in the context of the High Level Meeting on financial issues.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"(…) we have established a close cooperation with the FSA through the Monitoring Meetings, and we hope this good cooperation will continue in the future with the aim to achieve equivalence in the accounting field."

5 – Privatisation of Japan Post

Highlights:
One year after the start of the 10-year privatisation process, Japan Post entities have developed new business lines, tie-ups and alliances, and are requesting authorization of further expansion into new businesses. The private sector remains worried and is strongly objecting to these units expanding operations while the government still owns their shares, which could be seen as implicit government guarantee. A level playing field is not yet in place.

Case history: first raised in 2002, discussed in RRD in 2007. The Japanese reply delivered in December 2007 does not remove EU concerns. The removal of deposit / maximum insured amounts caps for the postal saving banks and postal insurance companies is first raised in RRD in 2008.

Privatisation process of Japan Post and misperceptions on implicit government guarantees

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 Japan Post entities and their private competitors. Transparency in the Japan Post privatisation process is also vital to ensure that transition to the private sector will be conducted smoothly and fairly.

Japan Post Holdings Co. is planning to list Japan Post Bank (JPB) and Japan Post Insurance (JPI) 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). The completion of the privatisation process of JPB and JPI should take place within 5 years from the listing (i.e. by 2016).
The EU considers that 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 towards eliminating misperceptions on implicit government guarantees.

Expansion of activities/removal of caps

JPB and JPI have been supervised by the FSA since last October in accordance with the Banking Law and the Business Insurance Law. FSA established the Office for Postal Savings and Insurance Supervision last October to oversight their governance system, risk management system and compliance management. The FSA considers that JPB and JPI meet the licensing criteria for banking and insurance businesses, but they need to improve their risk management and compliance management capability further before expanding their business scope.

JPB and JPI are also subject to provisions of the Postal Services Privatisation Law, which require them to get an approval from FSA/MIC for their expansion of business scope on the basis of opinions by the Postal Services Privatisation Committee (PSPC). PSPC's judgemental criteria for the expansion of business scope are (1) how new business affects JPB and JPI, and (2) if the level playing field is ensured. The FSA makes its decision on the expansion of business scope by taking account of their capability in terms of risk and compliance management required by the Banking Law and the Insurance Business Law.

Since October 2007, the following business expansions have been authorised:
- on 19 December 2007: syndicated loans, trading of public bonds and securities, acquisition and transfer of loans, derivatives trading, and reverse repo transactions;
- on 18 April 2008: credit card business, sales of life insurance products such as individual variable annuity, and brokerage of allied bank's housing loans.

On April 1st, JPB and JPI submitted requests for changing the regulation and allowing, respectively:
- JPI to increase the maximum insured amount from 13 million yen to 20 million yen;
- JPB to remove the 10 million yen per person cap on postal savings.

The increase in the maximum insured amount should be approved only if the notion that JPI is backed by implicit government guarantee is dispelled and risk management is improved. The GoJ should completely remove implicit government guarantee, before the cap on postal savings is lifted.

According to the Japan Post Privatisation Law, the MIC should ask PSPC for a judgment of appropriateness, when the Postal Delivery Company plans to launch a new business. In the recent case of the Postal Delivery Company launching a virtual shopping mall service, it did not ask the MIC for approval, arguing that this was not required because it was included in the "Business Succession Plan" published in 2006. However, the Plan was only published in summary form, and therefore the entirety of the Plans is not publicly known.
In this context, it is impossible for any third party to make comments on a possible new business authorisation for the Postal delivery Company, which is contrary to transparency rules and better regulation policy.

Ensuring open and fair access to the Post Office network

A nationwide post office network will be maintained to continue universal mail service. JPB and JPI will continue to offer their financial services nationwide through the existing over-the-counter network of the Post Office Company.

JPI's decision, announced at the end of February 2008, to form a tie-up in product and system development with Nippon Life Insurance Co., the largest private-sector life insurer in Japan, marks a turnaround from the previous stance adopted by Japan Post Holdings Co., which had established roughly equal relationships with

private-sector life insurers in product sales. With a combined 67 million policies, the two control more than one-third of the market for life insurance policies for individuals. As they start selling jointly developed high-end life insurance policies and third-sector products like cancer insurance, concerns are growing among other life insurers that they could keep competitors out of the post office network and increase their market dominance.

In this context, the EU recommends that GOJ ensures 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 EU regrets that the MIC has not replied to its offer of organising an exchange of views at expert level on postal reform issues, given the meaningful EU experience in opening-up the EU postal sector. The EU is convinced that a dialogue between EU and Japan experts will be mutually beneficial and therefore would appreciate receiving a reply on its offer of enhanced cooperation in this field.

In addition, the EU would appreciate more transparency in the MIC plans to gradually open up Japan Post mail delivery services to competition. In particular, the EU would be interested to know more about the follow up given to the recommendations issued by the MIC advisory panel last year.

Ensuring equal treatment of EMS with private express carriers

The Postal Delivery Company is expanding more and more into the international logistics market. After last year's decision to cooperate with China Post in Express Mail Service (EMS), it disclosed a comprehensive partnership with La Poste to deliver small packages when it enters international logistics services for shipments between corporations around October 2008. Such an expansion into international markets 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.

The EU welcomes the efforts made by the GoJ towards ensuring equal treatment as regards transportation regulations: the National Police Agency (NPA) has declared that vehicles carrying Yu-pack and EMS shipment will not be exempt from the Road Transportation Law. But in practice this is not being enforced due to local police agencies seemingly having difficulty in identifying JP postal vehicles carrying EMS versus 'regular' postal items.

EMS continues to enjoy preferential treatment as regards security regulations (which call for non-inclusion in cargos of such dangerous or illegal objects such as explosive, radioactive or toxic substances, narcotics, etc.) and customs. For instance, EMS import shipments containing quarantine related goods are released from airport facilities together with other postal related shipments without being checked by the Ministry of Agriculture, Forestry & Fisheries (MAFF) and Ministry of

Health, Labour & Welfare (MHLW). This procedure differs from that of the private-sector shipments containing quarantine items. These cannot leave airports until all relevant MAFF and MHLW inspections have been completed.

The MIC justifies such preferential treatment by considering EMS as falling under the universal service obligation. Being a competitive, value-added service, the EU reiterates its views 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. A further revision of the Customs Law in this respect would be a significant step towards a level playing field for private express carriers.

Cross-subsidisation between universal service and competitive services

Equal treatment of EMS with private express carriers also means that no cross-subsidisation should occur between the protected universal postal service and EMS, which is a competitive business.

When approving the joint venture between Japan Post and Sankyu, PSPC gave assurances that Japan Post had been instructed to ensure transparency of accounting procedures regarding the co-use of universal service operation processes and assets for any new competitive services. However, the mechanisms to achieve this and ensure ongoing compliance with this requirement are not yet known, nor is there any commitment that once developed they will be accessible to the public.

Reform proposals

The EU requests the GoJ to consider the following proposals, some of which were already submitted in December 2007:

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 reply to the EU offer of enhanced cooperation at expert level in the field of postal reform issues, which was presented in the RRD High level Meeting of December 2007;

c) To inform the EU of recent measures taken to dispel the notion of implicit government guarantee in the general public;

d) To organise public offerings for JPB and JPI as early as possible;

e) To give a greater voice to Japan Fair Trade Commission (JFTC) in the postal privatisation process. In addition, the EU would welcome to be updated on the views of JFTC as regards the whole privatisation process, and more particularly the issues of access to the postal network, cross-subsidisation between entities and between activities of a same entity, and expansion of business of all Japan Post entities;

Expansion of activities

f) To strongly limit the expansion of business scope for JPB and JPI, as well as leave the caps on postal deposits and insured amounts untouched, until these two companies are fully privatised;

g) To explain the reasoning behind the authorisations given for business expansion since October 2007; how the two criteria of the impact and level playing field were taken into account and their respective weights in the opinion of PSPC; did due impact assessments take place before the authorisations; how the impact on the private sector was taken into account in the MIC and the FSA decision to authorise business expansion; what the opinion of the FSA is as regards risk management and compliance management capability in view of any new business expansion;

h) To make sure that all new businesses planned by the Postal Delivery Company be notified to the MIC (and further to the PSPC) for approval so that all third parties have the opportunity to raise comments;

Access to network

i) To ensure that the current transition during which Japan Post Bank, Japan Post Insurance and Japan Post Network are all subsidiaries of the Japan Post Holdings Co. does not create bias as regards access to the network of post offices. In this regard, the GoJ should take measures to ensure that the conditions to access the network are clear and public;

Mail delivery sector/express mail service

i) To increase transparency in the planned process to further open up the mail delivery sector;

j) To treat EMS as a competitive service, not falling under the universal obligation service, and therefore apply to EMS the same rules,

regulatory treatment and customs clearance procedure which apply to private carriers;

k) To devise a method by which local police agencies are able to apply the Road Transportation Law in an equitable manner;

l) To suppress the discriminatory treatment that only favours EMS shipments with regard to the import clearance process (no quarantine shipments should be transported out of any international airport facilities without being subject to the same inspections and approvals by MAFF and MHLW as those which private sector shipments are subjected to);

Cross subsidization

m) 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;

n) To ensure transparency of accounting procedures regarding the co-use of universal service operations processes and assets for any new competitive services in the case of the joint venture with Sankyu.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007

"I would like to recall that we, **in the EU, are following closely the development of this process**, which is a complex one, covering postal services aspect and financial services aspects. Our main concern is that a level playing field is ensured between the successor entities of Japan Post and private sector operators.
This applies in particular to:

1) the expansion of business scope for Yucho (Japan Post banking entity) and Kampo (insurance entity) which should remain limited and carefully assessed.
2) EMS activities where we would like to see equal treatment with similar operations by private express carriers.

In terms of concrete proposals:
1) We would welcome that impact assessments are duly conducted for any business scope expansion for Yucho and Kampo
2) We would like to offer to share our experience on the opening-up of the EU postal sector by organising a meeting at expert level in margins of the next RRD in Brussels or in margins of a next Universal Postal Union meeting in Geneva."

6 – Air transport

Highlights:
While Japan remains one of the EU's most important air transport partners the relationship is not being exploited to its full potential and should be given more momentum. The EU welcomes that Japan now recognises the need for, and mutual interest in, amending the existing bilateral air services agreements between Japan and a number of EU Member States to bring these into conformity with Community law and acknowledges progress in this field. It is hoped that the encouraging signs of emerging liberalisation of Japan's aviation sector coupled with the expansion of the two main airports in Tokyo over the next two years will provide new opportunities to stimulate EU-Japan aviation relations and to resolve the main outstanding deficiencies.

Case history: first raised in 1999, discussed in RRD in 2007. The Japanese reply delivered in December 2007 does not remove EU concerns. Some regulatory issues first raised in RRD in 2008. RRD proposals related to investment are addressed in the chapter on investment.

General comments

In contrast to the EU's aviation relations with other key partners, including notably in Asia, EU-Japan air traffic has stagnated in recent years and continues to be severely restricted by the existing bilateral air services agreements. The current bilateral arrangements between Japan and EU Member States constrain the development of the travel market between Europe and Japan and are damaging to the interests of both European and Japanese consumers.

Moreover, most of the bilateral air services agreements remain legally vulnerable, owing to the absence of Community designation. Air transport relations between the EU and Japan are very important so restoring legal certainty remains a crucial first step in further developing aviation relations. The EU welcomes that Japan now recognises the need for, and mutual interest in, amending the bilateral air services agreements to bring these into conformity with Community law. The EU appreciates the gradual progress being made by the Japanese Authorities in this respect through bilateral negotiations in recent months with some EU Member States. It is important, however, that this process is completed as a matter of priority and that the amendments agreed on a bilateral basis are legally binding. It was with a view to ensure such a full and rapid restoration of legal certainty that the European Commission proposed a Horizontal Agreement between the Community and Japan. This invitation remains open and would be by far the most efficient way of restoring full legal certainty.

In spite of some progress also in other areas, many of the regulatory and infrastructural issues mentioned in earlier EU RRD proposals still remain to be adequately addressed.

The EU and Japan have much to gain from closer cooperation in a broad range of areas of aviation and the EU welcomes Japan's intentions to liberalise its aviation relations with key partners and wish to develop cooperation further. At the April 2008 Summit, leaders expressed their expectations that Japan and EU Member States would address the outstanding issues relating to the bilateral air services agreements. Restoring legal certainty 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 a broad bilateral regulatory dialogue, covering issues related to security (including the treatment of liquids), safety, airport capacity, air traffic management, market access and related "doing-business" issues.

Distribution, pricing and filing issues:

While progress has been made with regard to pricing flexibility for airlines to better reflect market conditions, pricing freedom and transparency remain restricted and filing and other procedures unnecessarily bureaucratic. The common perception remains that the pricing and distribution mechanism for air travel in Japan is still neither as efficient nor as consumer friendly as it should be.

The bilateral air services agreements still require airlines to file their fares for prior approval by the authorities thus restricting airlines in setting prices as they wish. This suppresses competition leading to higher prices than necessary for both European and Japanese consumers. Regulatory authorities including competition authorities already have the means to intervene in cases of abuse and monitor the market by other means if needed. Liberalisation of the pricing system, with suitable oversight from competition authorities, would stimulate passenger numbers and have wider positive impact on business, tourism and the wider economy.

Industry representatives believe that the Japanese authorities should further deregulate the distribution, pricing and settlement of airfares in Japan so that carriers can publish competitive net fares in a transparent fashion directly to the consumer, including over the Internet. The filing of prices is currently required to be done through the OFC (Official Filing Company) which moreover charges a considerable cost. The EU airlines operating to Japan would at least hope that carriers could file directly to the relevant ministry (MLIT).

Capacity issues

While the EU welcomes the increases of airport capacity in Japan and notably at Narita and Haneda from 2010, the EU is concerned that the full capacity may not be exploited and that the use of some of the additional capacity will leave EU carriers in a relatively disadvantageous situation compared to carriers from other regions of the world e.g. as a result of the "1950 kilometer perimeter" rule applied at Haneda and by not bringing as much incremental capacity for European airlines from airport expansions as they would wish to see.

We note in particular proposals to open up Haneda to scheduled flights to Asia but not Europe. This could put both European and Japanese carriers at a disadvantage

to Asian carriers flying indirect Japan-Europe routes. The expansion of the Haneda airport with a fourth runway from 2010 may allow international flights (rather than only domestic and within-Asia) but only during night hours. Time-zone differences mean European carriers would find it difficult to arrive in Tokyo at night hence rendering this possibility of little if any use in practice.

The planned expansion of Narita and Haneda airports represents a unique opportunity for a liberalisation of airport use and slots in the Tokyo area. The number of slots should be increased as far as reasonably possible (ref. proposal by the Council for Promotion of Regulatory Reform to increase the total number of slots in Tokyo from currently approx. 500,000 beyond the currently planned future level of approx. 625,000 up to a level of approx. 1 million slots). Furthermore, the allocation of the slots at both airports should be liberalised as far as possible to allow the market to decide the most efficient use of the infrastructure. The scope for airport expansion in Japan could become a missed opportunity for Japan and risks reducing Japan to a secondary air transport market/hub in Asia after other key hubs e.g. in South Korea, China and Hong Kong. If Japan wishes to avoid this scenario, action is required. The currently restricted capacity situation means that it would be difficult for tourism from Europe to Japan to grow. Large seasonal differences in available capacity and in ticket prices are not efficient either for consumers or airlines.

The EU has therefore been surprised and concerned about reported attempts to restrict foreign direct investment in Japanese airports. If such attempts were to become reality, it would further hamper the development of competitive and attractive airport services in Japan. Japan should on the contrary encourage foreign investment in its airports. This would also be consistent with wider policy goals of increasing FDI.

Cost issues

High landing, navigation and other user fees charged by airport authorities lead to high prices which in turn contribute to tourism remaining underdeveloped. It also has a negative impact on the profitability of EU carriers flying routes to Japan. As a last resort, airlines may have to turn to other airports with more attractive cost structures for services where airlines do not depend on using airports in Tokyo but can use other Asian hubs (e.g. for flights to the US West coast). If the current situation in Japan continues, it is highly likely that carriers will increasingly use other Asian airports as hub.

The Japanese Government should therefore strive to further liberalise the use of airports and to significantly reduce the costs associated with the provision of air transport services in Japan in order not to lose out in competition with other Asian hubs. The most effective way of contributing to this would be to let airports compete more freely with each other in providing services.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To complete the process of amending the existing bilateral frameworks between Japan and EU Member States to include Community designation by launching the necessary practical steps as a matter of urgency and in a legally binding manner;

b) Japan is invited to consider the option of negotiating a Horizontal Agreement with the Community. If Japan continues to prefer amending all its bilateral agreements individually with EU Member States, the European Commission invites Japan to discuss a Memorandum of Understanding with it to set out the framework for future cooperation in other areas such as aviation security. In such an MoU, Japan could provide the necessary assurances that until the process of restoring full legal certainty has been completed, Japan will not exercise its discretion under bilateral air services agreements with EU Member States regarding ownership and control of Community carriers in relation to designation by EU Member States of Community carriers;

c) To further deregulate distribution, pricing and settlement of airfares, allowing airlines to flexibly offer competitive net fares in a transparent fashion directly to the consumer, including over the Internet;

d) To continue improving current policies on the usage of aviation infrastructure ensuring efficient and non-discriminatory usage and allocation of slots, access to down-town Tokyo and easier transfer between international and domestic flights;

e) To include flights from Europe (as well as other regions) in "routes suitable for Haneda";

f) To substantially reduce landing, navigation and other user fees charged by airport Authorities;

g) See chapter 1.1 on investment for EU RRD proposals related to investment in the airport infrastructure.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007

"The present situation of bilateral air service agreements is not legally sustainable. The Prime Minister agreed with President Barroso to pursue discussions with Member States. We are disappointed about the recent "informal" discussions with Germany and hope this issue will be solved during the negotiations with Germany scheduled next year."

7 – Maritime affairs

1. Maritime Policy

Highlights:
After the adoption of the Basic Act on Oceans by Japan in 2007, the EU sees interest of developing a regular dialogue with Japan on integrated oceans management. Better understanding of the Japanese policy is necessary in this regard.

Case history: first raised in RRD.

Background

The EU Integrated Maritime Policy based on the "Blue Book" adopted on October 2007 has started to change the way the EU policy is formulated and decisions are taken regarding oceans governance and in maritime sectors. Its main objective is twofold: on one hand to streamline and link up the EU policies dealing with oceans and seas and on the other hand to ensure that they allow the further development of economic activities on a sustainable basis.

The key action fields of Integrated Maritime Policy are surveillance, spatial planning, data collection and marine observation. These actions are not only meant to increase the volume of data but to improve the use of all available tools from different maritime activities.

With respect to the international dimension, the EU plans to intensify international cooperation by setting up regular High Level Dialogue meetings on integrated oceans management with its strategic partners, including Japan. Main issues of common interest under Integrated Maritime Policy are the following: maritime governance, UNCLOS work and other relevant maritime organizations or conventions, surveillance, marine observation / data collection, maritime security and safety, including the fight against piracy, or climate-change mitigation (e.g. carbon capture and storage).

Japan adopted the Basic Act on Ocean Policy on July 2007. A Comprehensive Ocean Policy Headquarters was established within the Cabinet Secretariat for the purpose of implementing the new ocean policy. At present, the Prime Minister serves as Headquarters Chief, while the Chief Cabinet Secretary and a newly assigned Minister for Ocean Policy will serve as Headquarters Deputy Chiefs. Its implementation is still in an embryonic phase.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) Sharing common interests on maritime policy, the European Commission would like to inform the GoJ of its readiness of setting up a regular High Level Dialogue on integrated oceans management;

b) The EU would like to invite the GoJ to present its Action Plan accompanying the Basic Act on Ocean Policy (adopted in July 2007) and its state of implementation.

2. Fight against illegal, unregulated and unreported (IUU) fishing

Highlights:
The fight against IUU fishing is a priority on the international agenda, e.g. in FAO, OECD, the United Nations, and a constant concern for most of the fishing nations. Exchange of information is appropriate in this field.

Case history: first raised in RRD.

Background

The EU adopted a regulation on 29 September 2007 to prevent, deter and eliminate illegal, unreported and unregulated (IUU) fishing, which will enter into force on 1 January 2010. The regulation seeks to ensure full traceability of all fishery products traded with the Community, by means of a **catch certification scheme**. The US also have recently adopted legislative measures concerning the definition of a list of nations whose vessels have been identified as engaging in IUU fishing or bycatch of protected living resources and deny entry of fishing vessels (certified "negative") to US ports.

Reform proposal

The EU requests the GoJ to consider the following proposal:

To share information with the EU on the potential measures taken or envisaged to be undertaken by Japan to fight against IUU fishing, except the ones related to the implementation of the measures taken by the Regional Fisheries Management Organisations.

8 – Motor vehicles

Highlights:
The EU supports GoJ's commitment towards international harmonisation of vehicle regulations and mutual recognition of type approval under the aegis of the 1958 UNECE Geneva Agreement and encourages to further strengthening its active role in this field. Business context remains difficult for innovative technologies.

Case history: recurrent issue. The adoption of UN ECE regulations was discussed in RRD in 2006. Technical guidelines for new safety technologies, including radar technology, and for urea selective catalytic reduction vehicles first raised in RRD in 2008.

1. Alignment with UN-ECE Regulations

The EU believes that the international harmonisation of automobile regulations is in the fundamental interest of all nations with a high interest in automotive trade, especially as the auto industry is a truly global industry in all aspects. The high number of UN-ECE regulations adopted by the EU is a clear sign of the strong commitment towards international harmonisation.

The EU appreciates the active role played by Japan in the UN-ECE forum. The EU also appreciates that Japan shares its view on the importance of the 1958 Geneva Agreement in contacts with other Asian countries as the only practical and realistic means for mutual recognition in the area of motor vehicles.

The EU welcomes the adoption by Japan of UN-ECE Regulations in 2007. The EU requests Japan to continue in its process of alignment of its domestic standards to international standards and to accelerate the adoption rate of UN-ECE regulations. Early adoption of the maximum number of UN-ECE regulations will help to build on and consolidate the improvements which have already been made in reducing the time needed for type approval of motor vehicles in Japan.

Currently, the Automobile Type Approval Test Department (NTSEL) requires an applicant who seeks approval for the use of a device which complies with an UN-ECE Regulation, to submit not only the ECE Certificate, but also test reports and the ECE Certification application documents. This additional requirement imposes an extra administrative burden on importers and goes against the spirit of the mutual recognition provisions of the UN-ECE 1958 Agreement on which UN-ECE regulations are based.

Reform proposals

The EU requests the GOJ to consider the following proposals:

a) To accelerate its adoption of UN-ECE regulations;

b) To streamline the approval process for demonstrating compliance with an UN-ECE Regulation by requiring the applicant to submit only the ECE Certificate.

2. Technical Guidelines for New Safety Technologies

Foreign innovative safety technology for vehicles (e.g. vehicles with autonomous steering or braking system, adaptative front lighting) is put at a disadvantage in Japan compared to the treatment granted to Japanese manufacturers at home. The process managed by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT), to finalize Technical Guidelines for New Technologies should take better account of the principles of good administrative practises, transparency and non discrimination.

The approval of use of new safety technologies is not part of the formal Japanese type-approval process. MLIT may establish Technical Guidelines to serve as a basis for the approval of certain new technologies in Japan. Such guidelines do not have the force of law. However, in practice, the Automobile Type-Approval Test Department (NTSEL) will not grant type-approval to a vehicle which does not comply with the relevant Technical Guidelines. In principle, the guidelines can be amended to accommodate safety devices installed in imported vehicles which achieve the same objectives but use different technology than that foreseen in the guidelines. In reality, amending the guidelines has proved difficult and time-consuming and the process is still perceived as giving little opportunity to foreign manufacturers to be part of the consultation. In addition, the approval procedure is neither transparent nor predictable.

The technical guidelines therefore act as a deterrent to the import of vehicles incorporating advanced safety features.

Reform proposals

The EU requests the GOJ to consider the following proposals:

a) To simplify the regulatory environment for vehicles, while preserving the integrated approach combining environmentally sustainable and safety measures;

b) To make clear in the preamble to each Technical Guideline that its requirements are non-binding and that any reasonable deviation to the technical parameter, which has no negative impact on safety, will be allowed. If the technical guidelines are considered to be technical regulations, notification to WTO should take place;

c) To establish a transparent procedure, involving foreign stakeholders in the consultation process, and prescribed timetable for establishing new Technical Guidelines and amending, or demonstrating compliance with, existing Technical Guidelines.

3. Technical Guidelines for Urea SCR (Selective Catalytic Reduction) Vehicles (HDVs-Heavy Duty Vehicles and Passenger Cars)

In June 2004, MLIT established technical guidelines for vehicles with a gross wehicle weight of more than 3.5t equipped with selective catalytic reduction using urea. On 26 August, 2008 MLIT extended the guidelines to passenger cars.

In accordance with a policy first established by the then Transport Technology Council in 1972, the technical guidelines provide that the urea SCR catalyst shall not release copper, and other banned metals into the atmosphere, during the period of use of the urea SCR motor vehicle. Some European manufacturers wish to use copper in their passenger car urea SCR catalysts since it provides a more efficient emission reduction performance. There is however no standard test procedure or specification of an appropriate limit for demonstration purposes.

Reform proposals

The EU requests the GoJ to consider the following proposal:

- **To develop a testing procedure that would permit the use of copper in urea SCR catalysts and inform the EU of new developments in this field.**

4. Use of short-range radar technology

Those European vehicle manufacturers, which use short-range radar (SRR) technology to implement automated or semi-automated for emergency braking systems, are not allowed to use the 24 GHz radio frequency band in Japan in the

present Japanese regulatory framework, in particular according to the technical guidelines for safety technologies.

The European companies concerned consider short-range radar technology as the most effective technology for emergency anti-collision systems, given its ability to track fast-moving objects precisely and to discriminate between them. The 24 GHz band is currently SRR's frequency of choice, since the SRR technology operating in this band is both at an advanced stage of development and relatively cost-effective.

In the EU, the Commission Decision 2005/50/EC of 17 January 2005 harmonises the use of the 24 GHz band by automotive short-range radars on a time-limited basis and under certain conditions, in particular with regard to the risks of interference with other applications.

The 79 GHz band has also been harmonized for long-term SRR use in the EU (Commission Decision 2004/545/EC of 8 July 2004). However, this technology is currently not considered cost-effective by elements of the automotive industry, with some pleading for the long-term use by SRR of a band closer to 24 GHz (the 26 GHz band) on a globally harmonized basis. While the 26 GHz band is already allowed in the US for this purpose, Europe is at the beginning of a review of the use of radio spectrum for SRR to be likely finalized by the end of 2009.

In this context, the EU considers that it would be valuable for it and the GoJ to share information and exchange of experience on the use of short-range radar technology in the field of automotive safety, including with the competent Authorities-the Ministry of Internal Affairs and Communications (MIC) and the Ministry of Land, Infrastructure, Transport and Tourism (MLIT).

The EU would like to encourage the Japanese competent Authorities MIC and MLIT to pursue discussions with business, including European companies, to reach a balanced decision on access to appropriate radio spectrum for short-range radar, with a view towards global harmonization. The Japanese Technical Guidelines for Safety Technologies should be adapted, as necessary.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To ensure that the discussions between the Japanese competent Authorities, MIC and MLIT, and business on the use of appropriate radio spectrum bands for short-range radar continue to involve all relevant stakeholders, including the European companies concerned;

b) To amend the Japanese regulations, including the Technical Guidelines for Safety Technologies, to allow the use of radar technology;

c) To exchange experience and discuss best practices with the EU, at expert level, on the use of short-radar technology in the field of automotive safety in particular on the means to allow the coexistence of

SRR with other spectrum users in the bands of choice, and with a view towards global harmonization of radio spectrum use.

Other relevant dialogue: spectrum aspects are adressed in the annual dialogue on information society between the European Commission and the Japanese Ministry of Internal Affairs and Communication.

9 - Customs

Highlights:
The EU and Japan are involved in a cooperative process to reach mutual recognition of their respective Authorised Economic Operator programs within the framework of the EC-Japan Customs Cooperation Agreement. Building upon the good and constructive joint work between the Commission experts and the experts of Japan's Customs and Tariff Bureau, the EU would like to invite the GoJ to clarify its views, in particular on the legal status of the mutual recognition foreseen.

Background

Achieving mutual recognition of AEO programs between the EU and Japan will facilitate trade and also increase end to end supply chain security. However, these aims can only be achieved if the mutual recognition is automatic, unconditional and relies on a clear legally binding basis. Japanese experts have raised the view that a legally binding agreement would be difficult to accept. This position raises concerns on the EU side.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To clarify its approach on the bilateral mutual recognition of AEO programs foreseen, including on its legal aspects;

b) To give assurance that a decision of the EC-Japan Joint Customs Committee on Mutual Recognition will be directly and automatically applicable in Japan.

Other relevant dialogue: Cooperation under the EC-Japan Customs Cooperation and Mutual Administrative Assistance Agreement via the EC-Japan Customs Cooperation Committee.

10 – Healthcare and cosmetics

10.1 Pharmaceuticals

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 and balanced 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 2007. The Japanese reply delivered in December 2007 does not remove all EU concerns.

Clinical trials and the registration and review of new drug applications

While recognizing regulatory reforms such as the establishment of the Pharmaceutical Medicine and Device Agency (PMDA) in 2004, efforts toward international harmonization of regulations, actions taken to improve the processing capacity/capability of PMDA by increasing the number of reviewers to solve the drug lag in Japan and better handling of development consultations, concerns remain with regard to the contents of consultation for clinical trials as well as reduction in the time for review and approval of New Drug Applications (NDA). European firms are keen to see the realization of the target review time which has been committed to be achieved by 2011. 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 voiced about the adequacy of the raised fees relative to the drug assessment and services rendered by this body.

Protection of intellectual property rights

The EU welcomes that the MHLW issued a notification in April 2007 which extends the re-examination period for drugs with new active ingredients from 6 to 8 years, thereby improving the protection time for the data submitted for drug registration purposes. It would like to continue to share its experience with the GoJ in this field. The EU would like see the extension of the period to 8 years applied similarly to new combination drugs, drugs for new indications and drugs with new

administration routes. 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.

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 and provide data on average drug application processing time ;

b) To improve the environment for innovation, namely by further extending and expanding data protection.

Other relevant dialogues: European Commission-Japan confidentiality arrangement, EU-Japan IPR dialogue.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007

"We welcome the extension of intellectual property protection for new drugs to 8 years. We hope that the increase of staff of PMDA (Pharmaceutical and Medical Devices Agency) will lead to streamlining and shortening of the approval time."

10.2 Vaccines

Highlights:
The lack of predictable and transparent guidelines for vaccine's approval in Japan makes it almost impossible for European companies to enter the Japanese human vaccines market. The EU acknowledges that the Japanese Ministry of Health, Labour and Welfare (MHLW) recognizes the need to reform the field of preventive healthcare ("Vaccine industry vision"), in a context of challenges such as aging population, low birth rate and growing economical healthcare burden for the Japanese economy. It also notes more intensive discussions with business, including foreign companies, in the first semester 2008.

Case history: first raised and discussed in 2007.The Japanese reply delivered in December 2007 does not remove EU concerns.

Background

Europe is the world's leading region for innovative vaccine research, development and production- However, to date foreign vaccine manufacturers account for less than 2% of the Japanese human vaccines market, the second biggest potential market of vaccines worldwide, even though these same foreign companies account for about 38% of the Japanese pharmaceutical market.

The main obstacle for EU industry in accessing the Japanese vaccines market is the lack of transparent and harmonized clinical, regulatory and technical guidelines for approval in Japan of globally used vaccines. This makes it unpredictable whether new vaccines will be approved or recommended by public Authorities. An additional hurdle for non-Japanese manufacturers is the difficulty to identify the exact allocation of responsibilities in the Japanese administration. However, local manufacturers are known to manage developing and registering their products.

In addition, the Japanese technical specifications necessary for vaccine regulatory evaluation including clinical development, manufacturing, quality control and product release diverge considerably from those commonly used by the EU/USA/WHO.

The EU notes that the Japanese MHLW set up in April 2008 a study group to establish clinical guidelines for vaccines' approval. The European Federation of pharmaceutical industry and association (EFPIA) was invited to participate in this study group. This is a promising step as it will strengthen mutual understanding and exchange of best practices in this field.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To establish transparent and non-discriminatory clinical guidelines for vaccines development and approval, aligned with international practices, in particular with WHO and the EU;

b) To update and align the technical (product) specifications necessary for the clinical development, manufacturing and quality control of vaccines on the basis of international standards and best practices;

c) To ensure that a non discriminatory policy and treatment towards and among foreign companies interested in the Japanese vaccine market, including in the tendering process is implemented;

d) To facilitate these processes by further exchange of experience experience among experts between Japan and the EU;

e) To invite its experts to present a progress report at the next RRD meeting in Tokyo in December 2008.

Other relevant dialogues: Confidentiality Arrangement on pharmaceuticals between the Commission services and the Japanese Ministry of Health, Labour and Welfare; High Level Trade Dialogue (next meeting to be held on 30 October 2008 in Brussels).

EU concluding remarks, RRD high level meeting, Dec. 2007, Tokyo:

"We note that even if the EU industry is the world leader in this field, the foreign manufacturers represent only 2% of the Japanese market. The EU urges the GoJ to improve the transparency of legislation and implementing measures and offered to co-operate with Japan on this issue."

10.3 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, in particular the Japanese Red Cross, over importers, a tendency which is aggravated by the Japanese reimbursement scheme.

Case history: first raised in 2002, discussed in 2007. The Japanese reply delivered in December 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.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"EU remains concerned about a potential discriminatory effect of the "Blood Law" and would like to continue dialogue with EU companies and with DG Enterprises."

10.4 Medical devices

Highlights:
The EU takes note of the intention of GoJ to present an action plan to speed up the review for approval of medical devices by fall 2008 to make the Japanese market more attractive, following the adoption of the Basic Policies 2008. 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 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 RRD in 2007. The Japanese reply delivered in December 2007 does not remove many of EU concerns.

International harmonisation

a) Global Harmonisation Task force
The EU is pleased to see GoJ to continue to play an active role in the global regulatory harmonisation activities, such as the Global Harmonization Task Force (GHTF), and implement GHTF's recommendations, to the extent possible.

b) *International standards*
While taking into account Japanese active involvement in international harmonisation, the EU notes that MHLW's guidance on GMP remains not fully identical to the international standard ISO 13485 recognized in Europe. It considers that the acceptance of ISO 13485 by Japan would be a major step forward towards convergence and simplification.

The EU acknowledges the acceptance by Japan of foreign clinical data. But Japan's good clinical practices guidelines remain un-harmonized with international standard ISO 14155 on clinical investigation of medical devices for human subjects, widely adopted in the EU. This creates difficulties for manufacturers to conduct global trials including on Japan's territory.

EU-Japan bilateral dialogue

EU welcomes the further enhancement of cooperation with Japan by a confidentiality arrangement that is planned between EU and the GoJ for medical devices.

Approval process

The EU welcomes the forthcoming regulatory reforms in the field of medical devices, which were announced by the GoJ when presenting its Basic policies 2008

endorsed by the Cabinet decision of 27 June 2008. In particular, it considers it important that the action plan announced by the GoJ to speed up the review for approval of medical devices could be presented by fall 2008 as envisaged.

Furthermore, the EU acknowledges MHLW's initiative called "new medical device, medical treatment technology industry vision" and hopes that it would benefit to industry, including foreign companies as well as patients

The EU welcomes the efforts of GoJ registered so far to improve the transparency and efficiency of the approval procedure (e.g. increase in the number of reviewers, consultation on clinical trials, publication of review reports). The EU welcomes the work of the joint working-level practical task force on medical devices including IVDs and is of the opinion that administrative guidance regarding implementation at detailed and technical level remains to be clarified.

The "device lag" of products marketed in Japan long after introduction in Europe and elsewhere remains essentially unchanged.

While welcoming efforts toward international harmonization of regulations and reported progress made, EU industry continues to experience significant delays and difficulties as regards acceptance of foreign clinical data and other technical data accepted by the conformity assessment bodies and regulators in Europe and the United States.

EU welcomes the rise in personnel of PMDA in view of expediting procedures for imports. However it appears that medical devices need still more time to access the Japanese market despite the fact that the approval process within the Japanese Authorities has shortened. Due to stricter or more comprehensive requirements for applications, manufacturers need more time to prepare the dossiers which eventually has not reduced the "time to market" in the case of Japan.
Also concerns are voiced about the adequacy of the raised fees relating to resources, especially as regards pre-market review and quality systems auditing. These pre-market reviews and quality system audits have not yet been increased in line with needs.

Innovative health technologies

Many health technologies are characterised by short product life cycles and high innovation rates.
It is essential that GoJ implements measures to expedite the access, insurance coverage and payment of "new-to-Japan" health technologies and associated physician technical fees. 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.
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.

Reform proposals

The EU requests the GoJ to consider the following proposals, of which most of them were already submitted by the EU in October 2007:

a) To further streamline and improve 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 shorten the time period for market entry of medical devices, including for new health technologies 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:* as welcoming the possibility of a "package application" for QMS audits, to extend this package to cover all devices produced in the manufacturing facilities;

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 continue 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 continue to work with industry to develop 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 continue to work with industry to develop and apply guidance on changes in device design and manufacture which could clarify "partial changes" and "minor changes" and the relevant notification and review requirements.**

(B) Pricing and Reimbursement:

k) ***Pricing and Reimbursement:*** **to continue the work with industry, including Europe-based industry, to further improve the current pricing system; in particular in view of "functional categorization" improvement**

Other relevant dialogue: forthcoming confidentiality arrangement between the European Commission and MHLW.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"We would like the GoJ to:
- accept technical and clinical data generated under international standards and to create incentive to innovation in terms of pricing;
- continue cooperation with EU in the Global harmonisation Task Force and possibly in the framework of the confidentiality agreement."

10.5 Cosmetics

Highlights:
From 11 March 2009 onwards cosmetic products with animal-tested ingredients (with some exceptions) will not be marketed any more in the EU. Conversely, the EU has repeatedly raised with Japan the issue of acceptance of alternative (i.e. non-animal) tests.
The EU would like to reiterate the need to involve in due time all stakeholders in the consultation process when considering the evaluation of cosmetics functions.

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

Animal testing – trade in cosmetics
Animal testing has been a recurrent issue. The EU welcomes the clear commitment of Japan to accept alternative (non-animal) testing methods for cosmetics referring to methods validated/adopted by OECD.

Given the recent positive developments in international harmonisation, in particular in the **ICCR**, "International Cooperation Cosmetic Regulation", the EU sees an opportunity and good prospects to progress on its concerns related to animal testing. In this regard, the **International Cooperation on Alternative Test Methods** (ICATM) working group, set up in July 2008 has finalised a draft ICATM framework document which addresses three critical areas of cooperation: (1) validation studies, (2) independent peer review of the scientific validity of test methods, and (3) development of formal test method recommendations on alternative testing methods. This document will be submitted for endorsement by each region's regulatory authority this fall and made public when formally adopted.

The EU considers that the foreseen cooperation at the validation stage, in ICCR and bilaterally with Japan, is of high importance in order to avoid possible divergence of view at the time when OECD considers alternative methods.

Furthermore, the EU would appreciate if Japan can clarify definitively if it can accept the European validation, in addition to the use of alternative tests validated by OECD.

Confidentiality Arrangement
The Ministry of Health, Labour and Welfare and European Commission's Directorate General Enterprise and Industry have recognised the need to further improve their working relationship, in particular for increased co-operation in the field of regulation of cosmetic products as a means to better protect health and safety and dismantle technical barriers to trade affecting cosmetic products.

There is already a certain level of cooperation between these Authorities, notably in the framework of the International Cooperation on Cosmetic Regulation (ICCR). However there has been a desire to complement this multilateral forum by bilateral

policy and regulatory cooperation. In this context, the participants have prepared a "Confidentiality arrangement" to exchange more policy and regulatory information, including advance drafts of legislation and/or regulatory guidance documents as well as information related to the supervision of cosmetic products.

It was agreed that the confidentiality arrangement should take the form of an exchange of letters, and the Commission is currently waiting for signature on the Japanese side.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To increase cooperation at the validation stage through the ICATM framework, that would allow speeding up validation in the respective regions and at the OCDE;

b) To accept EU-validated alternative methods to animal testing.

Other relevant dialogue: forthcoming confidentiality arrangement between the European Commission services and the Japanese MHLW.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"This is an issue of common concern because the EU ban on animal testing might lead to serious trade disruption. We welcome the existing international cooperation (CHIC) but we would like to step-up our cooperation by setting up a formal group on validation of alternative methods."

11– Food safety and agricultural products

Highlights:
The EU would like to pinpoint eight priority regulatory issues. EU invites the GoJ to pursue discussions on EU 2007 RRD proposals related to other items (import controls including appeal procedures and hog casings) in other relevant frameworks, e.g. bilateral meetings in the WTO SPS meetings and other bilateral discussions. The EU is interested in having discussions with the GoJ on Maximum Residue Limits (MRL) and origin labelling.

11.1 Food additives and flavourings

Highlights:
EU considers it essential that Japan fulfils its commitment given in 2002 by the Japanese Government to complete without delay its assessments on the list of 46 priority food additives. Japan should improve the approval procedure to speed up the authorisations and take into account to a larger extent the scientific evaluations carried out by the international standards bodies.

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

Background

Many food additives of worldwide common use and recognised as being safe by international food safety bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) remain prohibited by Japan and therefore create trade irritants for EU export of food products.
In this regard, 600 substances which have been considered safe by international organisations are not allowed to be used in Japan. The EU remains strongly concerned of the slow path of the process review conducted by the Japanese Ministry of Health, Labour and Welfare (MHLW) to carry out evaluations for food additives and flavourings.

Upon the priority list of 46 food additives and certain flavouring agents established by MHLW to be considered for authorisation, 14 have been approved by September 2008. The EU is pleased to note that food additives Polysorbates (20, 60, 65 and 80) have recently been approved. Similarly, Japan should review some most commonly used preservatives (sorbic acid, potassium sorbate and sulphur dioxide) in order not to penalise imported food.
The length of the approval procedure however seems to be unacceptable especially as all of these 46 substances have already been assessed by international bodies and have been proven safe and are used widely in different countries. Therefore the issue remains a major concern for the EU and an irritant for trade relations.

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

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To accelerate its review process of authorisation to finalise the priority list by the end of 2009;

b) To rely to a greater extent on the scientific evaluation carried out by the international bodies such as JECFA /CODEX Alimentarius;

c) To hold a meeting in Tokyo between the Food Safety Commission and the MHLW on the one hand and the EU, including the representatives of the EU27 Member States on the other, to share information and to exchange questions.

11.2 Imports of bovine products

Highlights:
Bovine spongiform encephalopathy (BSE) related restrictions imposed by Japan on imports of beef and beef products from the EU remain, despite the fact that the World Organization for Animal Health has classified most of the countries as "negligible risk" or "controlled risk". The EU encourages the GoJ to align its national risk assessment policy and legislation on OIE international guidelines.

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

Background

EU notes that the GoJ has not yet completed the assessments for those Member States which have requested for exports of beef to Japan. Recently, two Member States received a request to complete a third MHLW questionnaire in addition to the questionnaires under the responsibility of MAFF. The EU remains concerned that this deviates disproportionately from the EU's own inspection practices and that the risk assessment process causes unnecessary delays.

In this respect, EU would like to refer to the World Organisation for Animal Health (OIE) which has drawn up special recommendations on conditions under which trade should continue and has established official recognition of the sanitary status of countries as regards BSE risk.

In the case of "controlled risk" countries, the OIE recognises that trade in beef and beef products and cattle of all ages from a "controlled risk" country is safe, provided that certain slaughter and beef processing conditions are met, including the removal of specified risk materials. The measures taken in EU since 1989 have proven highly effective. Therefore recently two EU-countries have received a status "negligible risk" whereas 23 EU countries have been recognised as having a "controlled risk" at OIE's general session in May 2008.

Japan resumed the import of US beef in 2006, which according to the latest OIE categorisation also falls under "controlled risk". In view of these measures it seems unjustified, discriminatory and against WTO SPS agreement that Japan continues to ban the import of beef and certain other bovine products from the EU.

Reform proposals

The EU requests the GoJ to consider the following proposal:

a) To accelerate its review process to allow for an early lifting of the existing ban on EU beef. In this regards, the EU requests that GoJ ensures that the applications of all concerned Member States for trading bovine meat in Japan are duly processed and that in the first half of next year the first inspection missions will take place for the most advanced Member States;

b) To align its legislation with OIE guidelines on trade in beef and other products concerning BSE;

c) To establish fair, non-discriminatory and transparent rules for the import of bovine meat;

d) To hold a meeting in Tokyo between the Food Safety Commission, MAFF and MHLW on the one hand and the EU, including the representatives of the EU27 Member States on the other, to share information and to exchange questions.

11.3 Regionalisation

Highlights:
To speed up efficiently the process of recognition of regionalisation for EU product imports, consultations between the EU and GoJ, including at expert level, are a necessary step.

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

The EU has regularly requested Japan to establish an agreement on the process of recognition of "regionalisation" for products imported from EU countries. Bilateral

negotiations and evaluations between Member States and GOJ are frequently cumbersome and slow and there is a clear desire to create efficiency gains.

Furthermore, the EU is concerned that Japan applies regionalisation in a discriminatory way since the affected areas delimited on the Japanese national territory are dramatically smaller than the one delimited for the Member States' territory. The EU also notes that while Japan applies regionalisation zones with regard to the EU, these zones are bigger than deemed necessary by European Commission and Member States. The EU therefore considers it necessary that Japan takes into account the EU legal decisions taken up at a European level with respect to regionalisation of an outbreak of a notifiable disease in the European Community.

In addition, the EU invites the GoJ to summarize detailed technical information in order to allow each EU regional Authority involved (e.g. veterinary service) to make the necessary statements and to issue the documentation required.

Reform proposals

The EU requests the GoJ to consider the following proposal:

To recognise EU regionalisation decisions when applying import measures on products from the EU and to establish a pragmatic process to achieve disease-free status recognition within the shortest delays.

11.4 Phytosanitary Regulations

Highlights:
EU is pleased to note a more co-operative approach from the GoJ on EU RRD concerns related to the phytosanitary regulations applied to imports of fruit and vegetables. Further progress from GoJ is requested to strengthen the collaboration between the GOJ, the EU and its Member States when establishing new import requirements for fruit and vegetables.
The EU welcomes the progress in the field of the list of non-quarantine pests and encourages the GOJ to continue its work to extend the list of non-quarantine pests to the remaining organisms proposed by the EU.

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

Access to the Japanese market for fresh fruit and vegetables

The EU would like to remind Japan that it gave assurance of upcoming progress to facilitate application of protocols approved for one variety of a fruit to other varieties of the same fruit, such as the low temperature treatment against Med Fly (ceratitis capitata) during the last RRD High Level meeting in December 2007. The opening to the market to the Italian "tarocco" variety oranges has recently been

successfully completed, through the entry into force of a specific protocol which fixed the standards for cold treatment. The EU welcomes the willingness of Japan to consider extending the approval for one variety of a certain fruit to other varieties of the same fruit. Therefore, EU invites Japan to further 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.

Japanese list of non quarantine pests

The EU welcomes efforts of the Japanese Authorities made so far in identifying non-quarantine organisms- not subject to quarantine measures. The EU reiterates its request that the GoJ aligns its regulations with international standards. Concerning *Aphis fabae* and *Aphis gossypii*, the EU urges the GoJ to accelerate and finalise very swiftly the risk assessment related to Pest Risk Analyses (PRA), which already started two years ago.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To further improve to facilitate the application of protocols by extending the similar procedures to other fruit varieties.

b) To expand the list of non-quarantine pests including the remaining organisms and to inform the EU of the ongoing work on the risk assessment related to pest risk analyses and give assurance to the EU that this process be finalised shortly.

11.5 Requirements for *Listeria monocytogenes*

Highlights:
The EU notes a different regulatory approach between the EU and Japan on how to monitor and control a food-borne bacterium *Listeria monocytogenes* between EU and Japan. It is necessary to distinguish between food that supports growth of *Listeria monocytogenes* and food that does not support the growth of the organism.

Case history: first raised in RRD in 2008.

Background

While taking into account the ongoing discussions in the Codex Alimentarius, the EU considers it useful that expert discussions start deliberations on the differences in regulatory approaches on monitoring and controlling of *Listeria monocytogenes. L.monocytogenes* is a pathogenic bacteria which can contaminate food and cause a lethal food-borne infection. In this respect, it is important that one distinguishes

between food that supports growth of *Listeria monocytogenes* and food that does not.

EU shares with the GoJ similar goals to maintain high level public health and to ensure that the risks of food-borne illnesses are reduced to an acceptable level. EU applies severe measures on high-risk food, including strict controls for those types of food which can support the growth of *Listeria.* However, for the latter category EU follows the latest scientific evaluations and has set a limit of "below 100 cfu/g" whereas Japan's approach is based on zero-tolerance across the board.

Listeria monocytogenes standards are indeed currently under discussion in the Codex Alimentarius. As part of this international process the Commission asked the European Food Safety Authority (EFSA) for an opinion on Listeria, which was adopted on 6 December 2007. In the opinion it is concluded that compliance of ready-to-eat foods to limits of "below 100 cfu/g " or " absence in 25 g" at consumption would both lead to very low numbers of listeriosis cases. The Commission is therefore confident that Japan could achieve the same level of protection for public health and food safety by applying the EU limit of "below 100 cfu/g."

The requirement for zero-tolerance for all types of food products appears to be unnecessarily trade restrictive. In this respect the EU expects that Japan will bring in line the microbiological criteria for *L monocytogenes* with best international practice and the on-going discussion in the Codex Alimentarius.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To amend the Japanese regulations and introduce the advanced and internationally scientifically recognised regulatory approach which distinguishes food which supports the growth of *Listeria monocytogenes* and food that does not support the growth of the organism;

b) To share experience with the EU in this field.

11.6 Breeder's rights

Highlights:
The EU takes note of the intention expressed in December 2007 in RRD to monitor the breeder's rights situation.

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

Background

The EU recognises the significant (international) efforts made by the GoJ to step up the control of possible infringements of breeders' rights. A good funtioning system of Plant Breeders Right Protection depends however also on a minimum use of the Farmers Privilige Rights. The EU recognises the measures taken by the GoJ in this respect 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 urges the GoJ to steadily 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.

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.

11.7 Japanese new framework on consumer safety and traceability

Highlights:
The EU has noted that the regulatory proposals on origin labelling and traceability of food products have been subject to discussion amongst the relevant ministries.

Case history: first raised in RRD in 2008.

Background:

Earlier this year proposals on traceability and origin labelling circulated amongst the various ministries. One of the proposals suggested a mandatory system for the labelling of the country of origin for ingredients of processed food. The EU feels that such a system would be impractical. Producers change the source of ingredients throughout the season and they can not change the label every time they source from a different country. It is also not easy to separate an ingredient when it is sourced from two or more different countries and accordingly it may be hard to tell from which country the ingredients come. We feel that a *voluntary system that allows for standard-setting by the Government*, such as the one used in the EU, would be more appropriate.

Reform proposals

The EU requests the GoJ to consult with all stakeholders before any other new requirements are imposed on importers of products from abroad. The EU invites the GoJ to have bilateral discussions at expert level with a view to reporting to the next RRD High Level Meeting in Tokyo.

11.8 Organic food certification

Highlights:
The equivalency granted in 2001 to the EU organic farming production rules and inspection has been put into question in practise by the Japanese Authorities, especially since 2006, on a unilateral basis. The EU still notes onerous administrative and financial obligations imposed on European certifying bodies competent for organic food, including obligations of re-registration and has not seen progress in this field.

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

EU concerns

While the EU and Japan have been committed in a bilateral equivalency process on organic farming production rules and inspection, the equivalency granted by the Japanese Authorities to the EU organic system in 2001 has been even less operational than before, following the implementation of the revised JAS law[5] since 1 March 2006. Despite efforts announced by the GoJ to reduce administrative burden (see the December 2007 Japanese reply to the EU RRD proposal), the EU remains concerned by the cost and administrative difficulties imposed on the European certifying bodies interested by the Japanese market or already registered under the previous Japanese registration process. The registration tax to use the JAS logo for Japanese consumer recognition and acceptance of the European organic products, the costly on-site inspections in the EU imposed by Japan and the incremental administrative burden for the new registration under the revised JAS law are considered to be deterrent by the European certifying bodies. This affects the supply of organic products from the EU to Japan.

Despite the December 2007 Japanese reply on the Japanese market access conditions, the EU has come to the conclusion that Japan, whilst officially granting equivalence to the EU organic control system, is not granting workable market access to the EU organic products without re-evaluating case-by-case the European certifying bodies which theorically have benefitted from the equivalency granted by Japan since 2001.

[5] Japanese revised law on standardization and proper labelling of agricultural and forestry products

While taking into account the advanced process of recognition of equivalence by the EU of the Japanese certifying system on organic products, the EU calls on Japan to fundamentally reconsider its restrictive approach on equivalency. The EU is strongly concerned that lawfully produced organic products from the EU can not be exported and freely traded on the Japanese market and that its certifying bodies can not make use of the official Japanese labelling required for the Japanese market.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To implement the equivalency granted to the EU in such a way that European organic products in conformity with the EU legislation have complete access to the Japanese market, including the use of the Japanese official logo;

b) Until such measures are in place, to give clear assurance that administrative burdens and financial costs imposed on the European certifying bodies under the revised JAS law are minimised to avoid de facto discrimination with the Japanese certifying bodies and that the European certifying bodies already registered by the Japanese Authorities can continue their activities without having to restart the Japanese registration procedure.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"(…) we understand Japan is already trying to make all the efforts to minimise administrative burdens and financial costs deriving from the application of the new law. However, we would like to highlight that EU certifying organisations still feel penalised and face difficulties in complying with the new legislation."

12 – Wood standards

Highlights:
A good start has been made to better accommodate EU wooden construction goods under the Japanese standards for wooden construction materials and products and the Japanese Building Law in 2008. In this sense, even in the absence of a WBED meeting in 2008, the EU has been active, both through furthering the necessary administrative steps and, at a strategic level, in proposing, to establish more bilateral expert dialogues on specific items.
However, the EU would like to reiterate its RRD proposals. The EU is committed to pursuing these issues with Japan through all appropriate vectors. In this regard, it submitted a report, including proposals on the functioning of WBED framework, in September and invites the GoJ to react, as soon as possible.

Case history: first raised in 2003, discussed in RRD in 2007. The Japanese reply delivered in December 2007 does not remove all EU concerns. EU proposals for additional bilateral technical working groups first raised in RRD in 2008.

General comments

Despite quite massive downturns in other regions, so far demand in Japan for wood-based construction remains relatively strong. This is so in both the residential and non-residential market sectors, with more than one million new houses already built in 2008, up on the 2007 figure. Conversely, Japanese domestic structural lumber production has continued to decline in the long term, increasing reliance on supplies from third countries. Amongst those, and as demonstrated at last year's WBED (Wooden Building Expert Dialogue) meeting, EU forests are an increasing, sustainably managed resource which can supply a significant portion of Japanese needs for high-quality, graded lumber and derived structural products.

Building upon the success of the Working Group on European White Spruce (Picea abies), the EU has reviewed its understanding of how to further improve longer term EU-Japanese joint work in the field of wood products. In this regard, the EU considers it appropriate to jointly establish additional focused technical groups in support of the overall WBED to make more rapid progress to mutual advantage, in support of the more formal WBED sessions. Accordingly, the EU side has prepared and sent in September 2008 a detailed report of the last WBED meeting, including some outline ideas about possible future progress, to MLIT via the EC's Tokyo Delegation. The EU invites the GoJ to react on this paper as it should provide a further basis for Japanese feed-back on the WBED process, as suggested in the concluding remarks expressed by the EU side in the RRD High Level Meeting of December 2007.

In addition to general remarks about the process as a whole, the range of issues on which the EU would be grateful for opinions include: the recognition process of

EN standards, CE marking, accreditation as well as the classification of European white spruce.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To recognize European White Spruce (Picea abies) as a separate tree and timber species from other spruces in the JAS glulam standard. 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) To agree to a further series of meetings of the Working Group established on European White Spruce; which build on the useful work done so far in this group. The first meeting should take place no later than the first quarter of 2009, using as one reference document an agreed report of the first meeting;

c) To recognize EN standards and CE marking of Structural Lumber and Glu-lam under MLIT Notification 1452 (2000) and - MLIT Notification 1024. (2001) (製材等の基準強度等の指定手続きガイドライン), respectively: The EU has encouraged its industrial collaborators to develop the necessary technical and administrative steps and looks forward to Japan's co-operation on this exercise;

d) To set up jointly with the EU a technical working group on the fire endurance tests and fire regulations, in order to allow the import by Japan of innovative, large-scale wooden products and systems, as well as fire-resistant materials from Europe. A first meeting should take place no later than the first quarter of 2009;

e) To set up jointly with the EU a technical working group to examine ways to simplify the accreditation procedure for testing organisations under the JAS/JIS (Japanese Agricultural/Industrial Standard) and Ministerial Approval Schemes, procedural issues. Amongst other issues, the working group should aim to ensure that internationally accepted data (such as ISO accreditation data) and documentation in English be accepted in the application to become a JAS-Registered Certification Organisation. Its first meeting should be no later than the first quarter of 2009;

f) To set up jointly with the EU a technical working group on 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. A first meeting should be held no later than the first quarter of 2009.

NB: The technical working groups proposed above should aim to produce agreed reports and report both to their respective parent authorities in the EU and Japan and to the WBED.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007

"We register progress made on wood products in the EU Japan expert groups such as the EU Japan wooden building expert dialogue and the working group on European white spruce and to invite experts to continue their discussions.

It will be useful that Japan, in addition to its explanations on Japanese requirements, gives its assessment of the functioning of the experts groups and progress still to be made to solve EU concerns. In this respects, the Commission will give a paper listing the issues on which Japanese assessment is needed.

To invite Japan to indicate in particular what room for manoeuvre there is to facilitate accreditation of European testing bodies for the Japanese standards relevant to wooden building products."

13 – 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 2007. The Japanese reply delivered in December 2007 does not remove all EU concerns, and new issues are emerging.

Registration of new veterinary medicinal products for food animal use

The EU considers it important that registration of new veterinary medicinal products for food animal use be better coordinated between different ministries and the timeline for the whole process be shortened. In Japan, the current system under the Pharmaceutical Affairs Law and the Food Safety Basic Law leads to a situation where three ministries, i.e. Ministry of Agriculture, Forestry and Fisheries (MAFF), Ministry of Health, Labor and Welfare (MHLW) and Food Safety Commission (FSC) reviews the dossier of a veterinary medicinal product registration from different standpoints at different times, often one after another, taking a long time before the final approval is granted. A product that is beneficial for animals and consumers cannot become accessible to the producers until several years after the same product becomes accessible in the international markets. A better coordination of the process clearly provides much faster registration and product accessibility in Japan.

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 proposals

The EU requests the GoJ to consider the following proposals:

a) To hold one ministry fully responsible for coordinating the registration of a veterinary medicinal product for food animal use, where all the review processes by different ministries proceed simultaneously and in a well coordinated fashion to avoid delays;

b) 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.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2007:

"We would like Japan to improve the intellectual property protection for food additives and antibiotics as already done for drugs."

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