2 October 2009

EU Proposals

for Regulatory Reform in Japan

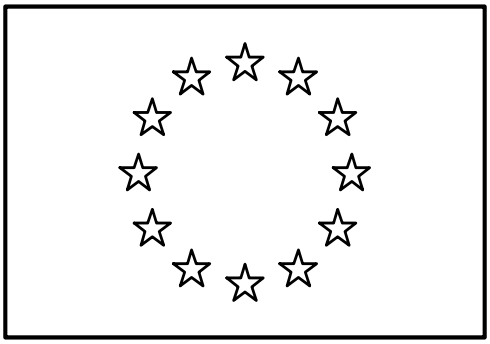

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Table of Contents

Introduction

The EU appreciates the sustained commitment of the Government of Japan (GoJ) to the EU-Japan Regulatory Reform Dialogue, which is in its fifteenth year. At multilateral level, together with G20 partners, the EU and Japan have committed in particular to combat all forms of protectionism as well as to promote and facilitate global trade and investment. The adherence to the undertakings defined at the G20 summits held in Washington in November 2008 and London in April 2008 has been highlighted by the EU-Japan Summit of 4 May 2009.

At a domestic level, on both sides, continued regulatory reforms are necessary to pave the way for economic recovery and sustainable growth, promote economic and social cohesion and ensure long term fiscal sustainability.

At bilateral level, regulatory dialogue can be considered as one of the tools contributing to a strengthened EU-Japan economic relationship bringing mutual and balanced benefit.

The EU side attaches importance to the main functions of the RRD process: a platform for dialogue on the regulatory policies envisaged or adopted by both sides; a basis for cooperative actions, including via exchange of best practices; a tool to strengthen mutual confidence and better understanding between European and Japanese regulatory authorities; a way to promote greater convergence on regulatory policies and practices; and a vehicle to remove non-tariff barriers to trade and investment.

PROGRESS REGISTERED IN THE EU-JAPAN RRD

The EU would like to highlight the following positive developments having an impact on the EU RRD proposals which have occurred since the RRD meeting held in Tokyo in December 2008:

SECTION INVESTMENT AND BUSINESS ENVIRONMENT

The adoption of the revised airport bill in Spring 2009 has addressed EU concern on a risk of discriminatory treatment in the field of airport infrastructure investment.

The EU is pleased to note simplification of the re-entry permit system following the adoption of an amendment to the Immigration Control and Refugee Recognition Act on 15 July 2009.

Exchange of information on each side's approach and policy with regard to Better Regulation has been pursued. The EU was pleased to present its Better Regulation policy in the March 2009 RRD meeting held in Brussels, as requested by the Japanese side. It invites GoJ to make a presentation at the forthcoming 2009 Tokyo RRD meeting.

SECTION GOVERNMENT PROCUREMENT

In Spring 2009, GoJ gave written explanations on the scope of application of the operational safety clause to railway equipment. The EU would like to thank GoJ for the follow up of this EU RRD proposal.

Process is underway to set up regular technical contacts between experts on e – procurement.

The EU welcomes indications from GoJ that it has been actively encouraging the use of open tendering process rather than selected or limited tendering procedure (see Japanese reply to item K of the EU RRD proposals for 2008 regarding government procurement). It also acknowledges efforts by GoJ to promote the "Comprehensive Evaluation Method" (items L and M of EU 2008 RRD proposals).

The EU is pleased that GoJ continues to discuss the issues of the Japanese public works thresholds and of access to the public procurement of local Authorities in parallel to the EU-Japan RRD, i.e. in the margins of WTO GPA coverage negotiations.

SECTION FINANCIAL SERVICES

In the field of banking services, the EU welcomes the enactment of the amendments to the Financial Instruments and Exchange Act (FIEA) in December 2008 and June 2009, and notes that further amendments were adopted in June 2009. Actual implementation will determine whether the reform of the firewall regulations and the establishment of control systems for preventing conflicts of interest will have positive impacts on the financial services industry.

The EU welcomes the pursuance of the Better Regulation Initiative as described in the Progress Status of Initiative toward Better Regulation published in July 2009.

In the field of insurance, the EU welcomes the constructive EU-Japan Insurance Dialogue engaged during meetings in January and June 2009, which aim to provide a forum for discussion and development of potential solutions to any insurance-related problems.

In the field of audit, the EU notes the adoption in September 2009 of the Framework for Inspection/Supervision of Foreign Audit Firms by JFSA on foreign oversight systems. The latter should clarify the approach towards non-Japanese Audit oversight systems. Along with the EU model, the Framework fosters mutual reliance, cooperation of audit oversight bodies and reciprocity.

In the field of accounting, the EU welcomes Japan's draft interim report on the Application of International Financial Reporting Standards in Japan adopted in June 2009. The EU strongly encourages Japan to pursue the convergence process.

SECTION AIR TRANSPORT

Following the common understanding reached on this matter, Japan has been engaged in revising the bilateral air services agreements concluded with EU Member States to include the principle of Community designation (see EU-Japan Summit Statement of 4 May 2009). The Commission services (Directorate-General for Energy and Transport) and the Japanese Ministry of Land, Infrastructure, Transport and Tourism agreed, in January 2009, to set up regular consultations on civil aviation.

SECTION MARITIME AFFAIRS

The EU acknowledges the willingness of GoJ to consider the possibility to set up a High Level dialogue on maritime affairs in 2009, building upon the exploratory discussions during the 2008 Tokyo RRD meeting. The main objective would be to strengthen exchange of information and share best practices on ocean management policy (e.g. EU integrated maritime policy/ Blue Book of October 2007, Japan's Basic Act on ocean policy of July 2007). It may also cover fisheries matters (e.g. implementation of the EU regulation related to the fight against illegal, unregulated and unreported fishing) for aspects relevant to Japan. Contacts are foreseen end-October on this. Given the positive discussions in this area, the chapter on maritime affairs has been removed in the 2009 edition of the EU RRD proposals document.

SECTION FOOD SAFETY AND AGRICULTURAL PRODUCTS

GoJ has previously committed to carry out inspections in the EU in Autumn 2009 in the context of the process towards lifting the ban on EU beef. The EU trusts that the Japanese competent authorities will therefore conduct these inspections before the end of this year, as agreed, and make their best efforts to move forward.

On the specific issue of listeria monocytogenes, the EU notes GoJ's interest to share best practices and strengthen mutual understanding with the EU.

The EU takes note of the establishment of the Consumer affairs agency on 1 September 2009. An expert discussion on origin labeling and traceability of food products was held in Spring 2009, via video conference.

DELETIONS:

With a view to ensuring greater focus and prioritisation, EU concerns on blood plasma (section healthcare and cosmetics), the list of non quarantine pests and the breeders' rights (section of food safety and agricultural products) as well as animal health products have not been included in this year's proposals. This should not be interpreted as meaning that EU concerns have been solved; discussions will continue as necessary in other frameworks during the following months.

OTHER COMMENTS ON THE STRUCTURE OF THE 2009 EU RRD PROPOSALS DOCUMENT:

In light of ongoing developments in Japan, the EU will submit an addendum to the present EU RRD document to cover financial issues (banking and investment services, insurance, auditing, accounting), the privatization of Japan Post, and possibly other issues as necessary.

A number of other additional specific issues (government procurement in the dredging sector, taxation and green industry technology) are still under consideration on the EU side and may be raised during the forthcoming 2009 RRD Tokyo meetings.

Similarly to last year, the 2009 EU RRD proposals document identifies other frameworks or discussion forums where the RRD proposals are also being addressed.

1 - Investment

1.1 FDI - Corporate restructuring – Corporate governance - [Taxation]

Highlights: The EU has noted GoJ statements since the last RRD Tokyo meeting maintaining the promotion of FDI into Japan as an important element in its economic policies in the context of the current financial crisis and economic downturn (e.g. FY 2009 Basic policies adopted by a Cabinet decision of June 2009). In particular, the EU welcomes the December 2008 revision of the "programme for acceleration of FDI in Japan".

On corporate governance, the EU welcomes the June 2009 reports from METI and FSA both recommending increasing the independence of Japanese company boards as well as the current efforts of Tokyo Stock Exchange to create a better environment for investors. The adoption of the revised airport bill in spring 2009 has addressed EU concern on a risk of discriminatory treatment in the field of airport infrastructure's investment (see 2008 RRD proposal). No progress has been noted on cross-border mergers/ tax-treatment and mergers-acquisitions in sensitive sectors.

Case history: First raised in 2005, last discussed in 2008 RRD. The Japanese reply delivered in December 2008 does not fully remove EU concerns.

1. General comments on the Japanese policy regarding FDI

FDI in Japan reached 3,6% of the Japanese GDP at the end of 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 towards this target has been slow and seems mainly to be due to foreign institutions strengthening the capital base of their Japanese subsidiaries in the midst of the current crisis, rather than an increase in M&A activity.

The EU welcomes "The Five Recommendations toward the Drastic Expansion of Foreign Direct Investment in Japan" (Shimada report) published on 19 May 2008 and calls for their full implementation. The Japanese Government revised its "programme for acceleration of FDI in Japan" in December 2008. However, additional measures will be needed. In line with the Five Recommendations, the scope of cases where FDI regulation is necessary and grounds for exceptions to the principle of non-discrimination between domestic and foreign investors should be clarified.

The EU has noted GoJ's intention to carry out comprehensive studies of foreign direct investment regulations. It would welcome further information regarding the timetable, scope and goal of these studies and encourages GoJ to take into account foreign experiences on FDI regulations. The EU is ready to share its experience in this field.

2. Merger-acquisition, Cross-border mergers and their tax-treatment

The environment for merger-acquisition in Japan remains too complex to be really attractive. This is in particular the case for the triangular merger scheme[1], which has so far achieved very limited results since the regulatory reforms of 2007: a foreign buyer still needs to set up a Japanese subsidiary, if none exists, which is cumbersome.

In 2008, merger-acquisition reached a low point with a value of 0.53 trillion yen for out-in operation compared to 7.46 trillion yen for in-out acquisitions.

The Shimada report on FDI of 2008 as well as the "revised program for acceleration of FDI in Japan" of December 2008 have recognised the need to improve the system and proposed operational recommendations. In particular, the EU welcomes reaffirmations since the December 2008 RRD meeting of the GoJ's commitment to assess the current merger-acquisition climate, e.g. by conducting a study on merger-acquisition with a view to facilitating merger-acquisition and further attracting foreign-owned enterprises.

3. Mergers and acquisitions in sensitive sectors

The EU would like to hear GoJ's updated assessment on the implementation and the impact of the notification requirement for merger and acquisition in sensitive sectors, which in particular was extended to include defence technology related sectors (Foreign Exchange and Trade Control Law and the amended Ministerial Order).

In line with 2007 Tokyo RRD meeting, it would be desirable that GoJ confirms that the principles of predictability, transparency and proportionality will be fully respected when implementing the law.

4. Corporate governance

The EU recognises the value of initiatives undertaken so far to strengthen corporate governance in Japan and encourages the GoJ to continue in this direction. Such initiatives should aim at ensuring the protection of minority shareholders.

Two reports released on 17 June 2009 by the Financial System Council's Study Group on the" Internationalisation of Japanese Financial and Capital Markets" and METI's Corporate Governance Study Group, set up in December 2008, have addressed the issue of the relationship between the low level of M&A activity and corporate governance structures.

The EU notes with interest the following proposals

- More independence on Japanese boards is needed, as a general matter, and, "most likely", more independent directors. METI proposes that each board should have at least one independent external director, on the basis of a comply-or-explain principle;
- Stock exchanges should ensure that shareholders have a say where new shares are issued to third parties and should take severe sanctions where shareholder rights are infringed. Furthermore they should require companies to disclose cross-shareholdings in their annual reports;

1 The New Corporate Law of May 2007 authorises cross border share for share merger to acquire a company in Japan.

- Companies should disclose the number of votes cast against a resolution at a general meeting and facilitate the exercise of voting rights.

The Tokyo Stock Exchange (TSE) is also making efforts to strengthen the protection of the right of shareholders. The Advisory Group on Improvements to TSE Listing System published some recommendations for creating a better market environment where investors feel secure in April 2009.

These reports acknowledge that greater protection of minority shareholders is necessary and that a system that is more understandable to foreign investors is needed. The EU believes that the recommendations go in the right direction and should yield concrete results for shareholders and investors in the short-term. The European Commission stands ready to share its experience with Japan on these issues.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. Investment

a) To fully implement the recommendations of the "Five Recommendations toward the Drastic Expansion of Foreign Direct Investment in Japan";

II. Cross border mergers

b) To inform of planned regulatory reforms to facilitate merger-acquisition with a view to further attracting FDI, including on the triangular merger scheme;

c) To revise accounting standards to limit cross-shareholding;

III. Merger and Acquisition in sensitive sectors

d) 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 to ensure that these restrictions do not restrict investment any more than is strictly necessary to meet these policy objectives;

e) To increase the notification ceiling for investment in sensitive sectors (at present 10% of the stocks of a company active in a sensitive sector);

IV. Corporate governance

f) To implement the recommendations of the Financial System Council and METI study groups, with a view to improving minority shareholder protection;

g) To inform the EU of the progress made in the follow-up of the recommendations of the Advisory Group on Improvements to TSE Listing System published in April 2009 and the revisions of the code of corporate conduct;

h) To improve the independence of outside directors by revising the definition of "outside director" in the Corporate Law so as to exclude insiders such as those linked to associated companies, major shareholders and business partners;

i) For listed companies, to make compulsory the requirements for the appointment of a sufficient number of independent directors in order to ensure that the interests of shareholders are adequately represented.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"We strongly believe that more balance in bilateral investment flows is needed and look forward to hearing about the contents of the revised FDI acceleration programme, which is due to released on 20 December 2008.

We urge GoJ to consider how the scheme of triangular mergers could be made more attractive (e.g. regarding tax deferral) and to expand the range of vehicles available for mergers.

We hope that GoJ will continue to consider improvement of corporate governance, including protection of shareholder interests, as a high priority. We note the new Corporate Governance Study Group set up by METI, which will report by June 2009 on issues like the independence of external directors and auditors.

Regarding the privatisation of Narita airport, we welcome positive indications regarding non-discrimination between foreign and domestic investors. We trust that this principle will be reflected in the revision of the Airport Development Law as well as the principles of transparency and proportionality.

On taxation issues, we note the inclusion of this subject in the Japanese preliminary replies and welcome the willingness of GoJ to pursue discussions in this field."

Other relevant dialogue: EU-Japan High Level Trade Dialogue (next meeting in end 2009 in Tokyo).

1.2 Legality of branches: quasi-foreign companies

Highlights: In its 2008 RRD reply document, GoJ claimed that it had received no complaints based on actual cases that Article 821 caused unreasonable adverse effect. While it may be difficult for an individual company to raise doubts concerning the legality of its own activities in Japan**,** concerns are still expressed on the lack of legal certainty. Companies in the financial sector are particularly affected.

Case history: First raised in 2005, last discussed in RRD in 2008. The Japanese reply delivered in December 2008 does not remove EU concerns.

Background (***for further details see the EU RRD proposals document of 2 October 2008)***

Article 821 of the Corporate Law has repercussions for many European companies, as a literal reading puts into doubt the legality of their business operations in Japan.

The EU would like to reiterate its call for a revision of the Corporate Law with a view to eliminating the legal risks entailed by Article 821. It invites GoJ to assess the impact of Article 821 on foreign companies, as provided for by the supplementary resolution adopted by the House of Councillors when the Law was enacted.

Reform proposals

The EU requests the GoJ to consider the following proposals:

To assess the impact of Article 821. In this regard, GoJ should organise an open consultation in which European and other foreign operators would be given an opportunity to participate.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"We regret that the Japanese government has not responded positively to our request for amendment of Article 821 of the Corporate Law, which we believe would contribute to creating an open and predictable environment for trade and investment."

1.3 Human resources

Highlights: The EU takes notes of GoJ's willingness to "improve the environment for foreign residents to live easily in order to attract foreign human assets, improve the facilities and services such as language services (…) where international financial functions are to be enhanced" (Program for acceleration of foreign direct investment in Japan of December 2008). The EU also notes GoJ's policy goal towards a greater acceptance of highly skilled human resources from overseas ("2009 Basic policies" document of June 2009).

Progress is noted on re-entry permit, as well as the negotiation of bilateral social security agreements (signature of agreements with the Netherlands and the Czech Republic in February 2008, Spain in November 2008 and Italy in February 2009. Negotiations planned with Ireland, Hungary, Sweden and Luxembourg).

Nevertheless, progress is relatively slow and more than half of Member States are not covered. For those not covered, no progress is recorded as regards double pension contributions.

On driving licences, no progress was made in the recognition of licences issued by the 12 Member States which have joined the EU since 2004.

Case history: first raised in 2002, last discussed in 2008 RRD. The Japanese reply delivered in December 2008 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' ability to secure highly qualified personnel and top business executives as well as on employees' private lives (e.g. the issues of re-entry permit, sponsorship of domestic staff, getting a driving license, investing money in a pension fund).

Re-entry permit

The EU welcomes the adoption, on 15 July 2009, of the Amendment to the Immigration Control and Refugee Recognition Act, which exempts the foreign resident from the need to apply for a re-entry permit as long as he/she re-enters Japan within one year of departure. The Amendment will enter into force within three years from adoption. Although it is not a total abolition of the re-entry permit system, it essentially removes the burden of foreign residents having to apply for the permit in advance of departure whenever they leave Japan.

The EU is grateful to the Japanese government for its effort to streamline the immigration procedure by also abolishing the Alien Registration Card system (*Gaikokujin-toroku-sho*)[2], and instead, issuing a Residence Card at the same time as the landing permission given at the port of entry. Although details are yet to be worked out, we understand that the requirements for reporting the place of residence (to the local authority) and other changes (to the Regional Immigration Bureau) will be kept to the minimum. Reporting by mail/email (e.g. for change of name/address of organisation which the resident belongs) would be authorised as far as possible.

Sponsorship of domestic staff

With a view to further improving living conditions of foreign businesspeople, it would be desirable to allow a broader-range of business executives to sponsor domestic staff, taking full financial responsibility, with appropriate protections against abuse.

Driving licenses

The GoJ has agreed to fully recognise the driving license from 15 EU Member States. When residing in Japan, holders of EU driving licenses have to exchange their European license for a Japanese one. However, holders of driving licence from the 12 EU Member states which have joined the EU since 2004 have to undergo tests of their driving

2 Under the current system, a foreign resident is required to obtain an Alien Registration card from the local authority of the place of residence, separately from the landing permission (residence permission) which he/she obtains at the port of entry.

capabilities. All EU driving licenses are issued under the same minimum requirements; therefore the GoJ should recognize all EU driving licences without differentiation. The EU would like to encourage the GoJ to continue looking for a satisfactory solution, using all avenues, including bilateral talks with individual Member States.

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 EU welcomes the conclusion of a number of bilateral social security agreements with EU Member States and the progress accomplished since last year. But in the absence of such agreements, foreign workers can only benefit from a partial refund system capped at 3 years. This arbitrary cap may create disincentives for staff to remain longer and therefore have adverse effects on companies' personnel management.

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 making 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 environment for foreign residents:

a) To make sure that the Amendment to the Immigration Control and Refugee Recognition Act is implemented in such a way as to minimise the burden on foreign residents;

b) To allow a broader-range of business executives to sponsor domestic staff;

c) To recognise the EU driving licenses of the 12 Member States who have joined the EU since 2004 on the same basis as driving licenses already recognised for 15 EU Member States;

II. Concerning pension schemes:

d) To conclude bilateral social security agreements with all EU Member States as soon as possible;

e) For EU citizens not yet covered by a bilateral agreement with a view to avoiding double pension costs:

- To increase the cap for the partial refund of contributions paid to the Japanese public system by foreign workers to 5 years instead of 3 years, as a first step towards allowing for a full remittance of mandatory contributions. This would be in line with the possible extension of the resident permit for some categories, from 3 to 5 years, following the amendment to the Immigration Control and Refugee Recognition Act adopted on 15 July 2009;

f) To ensure that contributions to foreign-based pension plans are subject to the same tax relief as contributions made to pension plans in Japan;

g) 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.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"Regarding re-entry permits, the GoJ indicated that draft legislation will be tabled before the end of the regular Diet session in 2009 *inter alia* with a view to reducing the administrative burden for foreign residents.

We also encourage Japan to accelerate negotiations with remaining EU member states on recognition of driving licences and on bilateral social security agreements.

We will provide a list of concrete areas where we hope to see certificates recognition for skilled workers."

1.4 Better Regulation, including transparency

Highlights: The EU welcomes restatement of the GoJ's commitment to regulatory and institutional reform ("Basic Policies" document adopted by a Cabinet decision of June 2009). It notes the announcement of reforms in Japan's policy-making structure and administrative practice as well as the restructuring of the Council for the promotion of regulatory reform. The EU strongly encourages the GoJ to give a higher profile to the Better Regulation approach across government and to apply it more systematically, on a horizontal basis.

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

1. General comments on Better Regulation

Better Regulation covers policy making from its initial conception to its implementation and enforcement and promotes the principles of transparency, impact assessment, simplification, codification and repeal of obsolete legislation.

The EU considers it appropriate that the exchange of experience on Better Regulation, initiated in RRD meetings since December 2007, be pursued on a regular basis in RRD meetings, as jointly agreed in RRD meetings of December 2008 and March 2009. In this regard, in the forthcoming 2009 Tokyo RRD meeting, the EU would appreciate that the GoJ gives an update on its Better Regulation policy and approach.

2. The public comment procedure ***(for further details see the EU RRD proposals document of 2 October 2008)***

The EU supports continuous efforts of the Ministry of Internal Affairs and Communications (MIC) to ensure that the public comment procedure, under the revised Administrative Procedure Act (APA) of 1 April 2006, is applied in all its aspects by the Ministries and Agencies: comment period of at least 30 days, sufficient time provided to consider the comments submitted when establishing administrative orders or regulations, responses provided as efficiently as possible.

The EU considers it important that the GoJ continues to publish an annual survey on the enforcement of the public comment procedure and promote better implementation of the procedure as necessary.

3. No-Action Letter ***(for further details see the EU RRD proposals document of 2 October 2008)***

The EU welcomes the Cabinet decision of June 2007 that brings improvements to the No-Action Letter (NAL) system[3]. 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.

4. Foreign stakeholders (***for further details see the EU RRD proposals document of 2 October 2008)***

The EU considers it important that, when new legislation is being considered, the GoJ allows foreign business to present its views in a timely way, including at the consultation stage, or during discussions on impact analysis and assessment, . The EU does not consider that, 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. 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.

The EU has in the past raised concrete cases which presented concerns about the possibility for foreign business to participate in consultation processes organised by Japanese ministries (e.g. Article 821; Foreign Lawyer System Study Group established by the Ministry of Justice and the Japan Bar Association in June 2008).

5. Regulatory impact analysis **(*for further details see the EU RRRD proposals document of 2 October 2008)***

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 new regulations. The EU welcomes the increased attention attached by the GoJ to RIA since 2007. In particular, it notes the publication

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

by MIC of the FY 2008 annual report on the policy evaluation in June 2009 and a study on the "competition assessment in the OECD and other foreign countries" in March 2009.

While appreciating the efforts of Ministries and Agencies to enhance the quality of policy evaluation as shown in the annual report, the EU reiterates its request that the GoJ extends the compulsory application of ex-ante evaluation of regulations to all fields of activity. The results on ex-ante evaluation of regulations should be made public and be subject to public comment.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. Better Regulation

a) To work towards a more transparent and predictable regulatory environment, including with regard to enforcement. The EU invites GoJ to maintain Better Regulation as a top political priority when reviewing or considering new regulatory reforms and to consider the possibility of making this approach more horizontal, across all government departments, and compulsory;

b) To continue to exchange experience on the implementation of Better Regulation and forthcoming developments in this area. In this regard, the EU would like to invite GoJ to make a presentation in the forthcoming 2009 RRD Tokyo meeting;

II. Implementation of the Japanese Public Comment Procedure

c) To continue to publish an annual report to assess how far the "public comment procedure" has been implemented by Japanese ministries and agencies. In this regard, the EU invites GoJ to inform it of the results of its assessment for FY 2008 and of improvements envisaged or foreseen;

III. "No-Action Letter"

d) To provide an assessment of the implementation of the "no action letter" system;

IV. Participation of European-affiliated stakeholders in the decision-making process

e) To ensure that foreign business is given the opportunity to present its views, in a timely manner, when a new regulation is drafted. More generally, 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;

V. Regulatory Impact Analysis (RIA)

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

g) 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;

h) To inform the EU on the follow-up envisaged to the MIC's study on the "competition assessment in the OECD and other foreign countries," in particular with regard to further improvement of the Japanese RIA system.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"We recognise the efforts made by the GoJ towards better regulation in the past few years. We would urge that they be continued and applied on a cross-sectoral basis. As regards involvement of foreign stakeholders in decision-making process, we would encourage that best practice be extended to all Ministries. We take note of GoJ's willingness to continue and develop information exchange with the EU in this field, including through the RRD meetings."

2 – Government procurement

Highlights: The EU believes that the benefits of open trade in areas covered by government procurement need to be secured and extended, in particular now that GPA coverage negotiations are taking place. It welcomes the continuation of a forward-looking bilateral dialogue with Japan on government procurement, and welcomes the prospect of in-depth exchanges in the area of electronic procurement. Benefiting from a reciprocal access for railways and urban transport is a top priority for the EU.

Similarly to the 2008 RRD edition, the EU would like to further discuss with Japan the issues of Japanese public works thresholds and of access to the public procurement of local authorities (cities/-*shi*, towns/-*machi* and villages/-*mura*), in parallel to the RRD framework, i.e. in the margins of the GPA coverage negotiations.

In the forthcoming RRD meetings to be held in Tokyo in Autumn 2009, the EU reserves the right to address the issue of dredging.

Case history: First raised in 2003, last discussed in 2008 RRD. While the Japanese reply, delivered in December 2008 and completed in 2009 Spring, increases transparency on the scope of the operational safety clause, major EU concerns have not been removed, in particular for railway procurement.

Background

EU firms still consider that doing business with the Japanese public sector is hindered by specific legislation and practices (lack of transparency, lack of single point of access, administrative obstacles, remedies, no English translation of procurement legislation).

1. Opening the access to railway and urban transport procurement

As indicated in previous RRD editions, access of globally competitive EU firms to the procurement of rolling stock by Japanese railway and urban transport operators is extremely limited. The EU strongly believes that this situation is explained by the extensive and excessive use by GoJ of Note 4 of Japan's Appendix to the GPA far beyond the scope for which this clause was originally intended. This leads to a regrettable imbalance that could lead to calls for the consideration of reciprocity clauses.

The EU thanks the GoJ for the written explanations on the scope of the operational safety clause. It understands that this clause applies to all substantial government procurements of goods and services by the railway and urban transport contracting entities. This consequently closes the Japanese market to EU competitors. Japan's procurement policy in this sector differs significantly from international practice. According to international practices, contracting authorities address safety issues by explicitly indicating in tender documents how they assess technical capacity and/or by including an explicit reference to existing technical standards (1). The EU would encourage GoJ to apply this approach when defining the technical specifications of public procurement in the fields of railway and urban transports.

Given the high level technical knowledge needed and to benefit from each side's experience, the European Commission would like to invite Japan to further discuss on the issue of technical standards, e.g. by setting up a bilateral expert working group.

Passenger safety is clearly the paramount concern both for Japan and the EU. Liberalisation of bilateral trade in railway equipment can be pursued in a manner which is fully compatible with this key objective. The European Commission considers it important to further strengthen mutual understanding on the EU and Japanese legislation/safety requirements for railway equipment and urban transport. In this regard, it would like to invite Japan to jointly organise/take part in an expert seminar envisaged in Tokyo by end 2009, e.g. back to back with the Commission-Japan expert meeting on government procurement held in the margins of the Tokyo RRD meeting (participation of experts from the Directorate-General Transport and Energy of the European Commission and the European Railway Safety Agency).

2. Single point of access for public procurement business opportunities

In the Internet age, single information portals listing all contract opportunities within the public sector have contributed significantly to efficient e-government and increased competition for public contracts.

The EU is convinced that such a system would contribute to greatly enhance transparency and efficiency of public procurements in Japan. Whereas central government's tender notices are all available (even electronically) in the national

Gazette (Kanpo), local tender notices are still published in various gazettes (Kenpo, Shiho or equivalent) and, where electronic, in an undetermined number of different electronic sites.

Therefore, the EU wishes to reiterate its RRD proposal that Japan centralises its procurement under a single website, equivalent to the EU electronic centralised tender database, "TED"[4]. It 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 at present.

The EU also notes that, in April 2009, the Japanese Keidanren called for GoJ to enhance transparency of public procurement, notably by setting up a virtual single access point.

3. 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 foreign companies. The revised GPA will introduce new provisions on electronic procurement.

The EU highly values its regular bilateral regulatory dialogue on public procurement with Japan. In this context, the EU reiterates its interest in pursuing cooperation on e-procurement, at expert level, notably by exchanging information on regulatory and technical developments in this area on a yearly basis. To reduce costs, such meetings could be organised via videoconference. Furthermore, the EU would also like to reiterate its invitation for Japanese procurement experts to attend meetings of the EU Working Group on E-Procurement as observers.

The European Commission has welcomed Japan's preliminary contacts following the 2008 RRD to find appropriate ways to discuss electronic procurement, in particular with the MIC and the Japanese Machinery Association.

To further progress, the European Commission wishes to organise a seminar on electronic procurement in the margins of the government procurement expert meeting back to back with the 2009 Tokyo RRD meeting.

4. Reinforce and extend the system of challenge procedures in the area of government procurement

An efficient public procurement framework requires an efficient remedies system to put pressure on contracting authorities/entities to award contracts in a fair and transparent

4 In its Suggestions for Accessing the Government Procurement Market of Japan (http://www.mofa.go.jp/POLICY/economy/procurement/q-a.pdf), the GoJ itself alerts potential foreign bidders that they should have sufficient knowledge of technical specifications like the Japan Industrial Standard (JIS), that distributors and manufacturers are often required to meet.

In the EU, 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), regardless of whether a specific procurement is covered by the GPA or not. Businesses to monitor calls for tender for their types of products, works and services thanks to the CPV (available in 22 languages). In 2007, public procurement opportunities worth 370 billion EUR were made available in this website.

manner. The remedy system should also guarantee that the competent authority for the challenge procedure is free of any conflict of interest.

The EU understands that, to implement the GPA, Japan has set up the CHANS ("Government Procurement Challenge System") whose powers are limited to the procedures of central government authorities (listed in Annex I of GPA) and public institutions (listed in annex 3 of GPA), both falling within the scope of GPA. It does not cover procurement procedures of local authorities (annex 2 of GPA).

In these circumstances, local authorities can establish themselves the bodies competent for challenge procedures. So far, the system seems rather unclear: suppliers do not know the names of these bodies in the different Prefectures; a situation of conflict of interest may be generated when the challenge body is also the contracting authority.

As a result, the EU would like to ask the GoJ to entrust challenge procedures to Japanese tribunals.

Moreover, the EU would like to ask the GoJ to make the CHANS or other challenge bodies competent for all procurement procedures in Japan and not only for procedures falling within the GPA scope. This would remedy a weakness of the present system: a European firm currently cannot challenge any award procedure for a contract mistakenly considered as falling outside the GPA on "operational safety" grounds.

Finally, the EU understands that the powers of the challenge bodies in Japan do not extend beyond written recommendations. Therefore, it encourages GoJ to ensure that these bodies are able to provide for rapid interim measures to correct breaches and appropriate remedy.

*5. In the short-term, a codified legal framework available in English; in the long-term, a more coordinated legal framework (**for further details see the EU RRD proposals document of 2 October 2008).***

It remains necessary that the Accounting Law and Local Autonomy Law be included in the Translation Development Program for FY 2010. This would give a strong signal of transparency to foreign suppliers.

In the long term, the EU encourages the GoJ to streamline, when necessary, and codify its procurement legislation. The Japanese legal framework for public procurement is a complex system of statutes and regulations which are scattered across different legal texts, dating back to the late 1940s and amended many 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.

*6. Removing administrative obstacles that EU firms face in Japanese public procurement (**for further details see the EU RRD proposals document of 2 October 2008).***

The EU reiterates its RRD proposal that GoJ removes the business evaluation procedure (*keishin*) and the compulsory registration before each procuring entity. These procedures cause unnecessary burdens for foreign suppliers, particularly in light of the possibilities offered by electronic procurement.

The EU would like to recall that one of purposes of the GPA is to ensure the possibility for companies established in the EU (and not necessarily established in Japan) to be able to directly bid for contracts in Japan.

In the revised GPA, the EU and Japan agreed not to adopt or apply registration systems (for the qualification of suppliers) or qualification procedures with the effect of creating unnecessary obstacles to the participation of their companies in each other's markets (cf. current agreed article on qualification of suppliers). The EU invites GoJ to clarify the operational approach it will apply in future, in light of these developments.

7. Towards broader technical specifications taking into account innovative solutions

Japan's technical specifications used in tenders are often too narrowly prescribed, in a way which does not allow bidders to bring innovative solutions. The EU has a very positive experience of expressing technical specifications in terms of performance rather than design or descriptive characteristics (cf. Article VI GPA). 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 the supplier's claims of equivalence.

8. Other business

The EU is interested to further exchange views with Japan on:

- Abnormally low tenders;
- Green Procurement.

Reform proposals

The EU requests the GoJ to consider the following proposals:

I. Opening railway procurement and ensuring adequate transparency

a) To abolish the Note 4 of Japan's appendix to GPA. As a first step, the EU calls for Japan to drastically reduce the scope of products and services covered by Note 4 in the very short term. To achieve this goal, the EU encourages the GoJ to work out recommendations asking the railway and urban transport contracting authorities to refer systematically in tender documents to technical specifications based on international standards or other relevant technical standards;

b) To discuss on a regular basis with the EU the safety and interoperability issues in the areas of railway and urban transport procurements. This would contribute to improve mutual better understanding on each side's regulatory policy and legislation, coordinate views and conduct joint work, e.g. on technical standards and innovative solutions acceptable in tenders;

c) To set up a joint working group at expert level to discuss the issues mentioned in points a) and b);

d) To encourage the competent Japanese Administrations to actively participate in the preparation and the seminars on railway equipment which the European Commission envisages holding in Tokyo in the following months;

II. A single point of access for public procurement business opportunities

e) To set up a free-of-charge electronic single point of access where all Japanese tender notices- central, regional and local authorities, public enterprises falling under the Japanese Procurement Law- are published and available, with summary notices in English or any other WTO language. GoJ is invited to launch this initiative by 2011;

f) The EU is ready to share its experience with GoJ. The TED (tenders electronic daily, http://www.ted.europa.eu) government procurement database ensures transparency and gives access to a huge array of business opportunities;

III. Regular dialogue on e-procurement

g) To hold regular discussions on e-procurement with the EU, e.g. on an annual basis by videoconference, to inform of policy and technical developments on each side, and to exchange best practices including on interoperability in the area of e-procurement;

h) To encourage the competent Japanese Administrations to actively participate in the preparation and the seminar on e-procurement which the European Commission envisages to be hold in Tokyo in the following months,

IV. Strengthening remedies procedures

i) To extend the Japanese system of challenge procedures to procurements not covered by the GPA;

j) To provide a consolidated list of challenge bodies of local governments covered by the GPA (Annex 2 entities);

k) To set up an independent challenge system that does not depend from any contracting authority and consider the possibility of entrusting Japanese tribunals with competence for challenge procedure;

l) To ensure that the challenge bodies can have binding powers regarding interim measures;

V. Simplifying, codifying and translating Japanese public procurement legislation

m) To translate the Accounting Law and the Local Autonomy Law into English in FY2010;

n) To simplify the legal framework between the central and local administrative levels,

VI. Removing administrative obstacles that EU firms face in Japanese public procurement (e.g. keishin business evaluation, compulsory registration)

o) 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;

p) To eliminate 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;

VII. Broadening technical specifications to allow « innovative solutions » to be taken into account.

q) To ensure that technical specifications issued by procuring entities at all levels do not rigidly prescribe particular design or descriptive characteristics, but also allow for "equivalent" solutions which meet the needs of the procuring entities in question. This approach is important for fostering innovation. It applies not least with regard to "green procurement".

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"The EU welcomes the willingness of Japan to engage in technical discussions on e-procurement.

Regarding railway procurement, there is a need to improve access to the Japanese market through an objective and predictable use of the "operational safety clause" in railway procurement. The EU recalls its request for a document explaining in detail the full scope of the operational safety clauses, in particular as to the goods, services and works covered.

The EU encourages Japan to establish a single point of access for all public procurement business opportunities, including local government as in the EU.

The EU confirms its request to have the General Accounting Law translated into English."

3 – Information and communications technology (ICT)

Highlights: The EU notes that in the Cabinet Decision of 3 December 2008 concerning the basic principles for FY 2009 budget's formulation, the GoJ will promote efforts to

make the country the world's most advanced IT technology, in a context of pursuing economic recovery.

Information and communications technologies play an essential and increasing role in the competitiveness of the whole economy and in the life of citizens. In this context, only a pro-competitive regulatory environment can foster innovation and greater choice for Japanese consumers and enterprises. In addition, in a world of fast-evolving technologies, global harmonization and reduced barriers allow services and products to be delivered at the lowest possible prices. Last but not least, in this sector regulators face the challenge of the growing convergence between telecommunications and broadcasting services.

In this context it is essential for Japan to complete and expand the reform initiatives launched in 2006 and to proceed with the institutional changes needed to make the implementation of ex-ante and ex-post regulation more efficient.

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.

Case history: recurrent issues, last discussed in 2008. The Japanese reply delivered in December 2008 does not remove all EU concerns.

Background ***(for further details see the EU RRD proposals document of 2 October 2008)***

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 view of the market position of the companies of the NTT Group, it is essential that the Japanese authorities continue to monitor the conditions under which interconnection and access are offered to other competitors. In the context of the discussion about a possible reorganization of the NTT Group, the EU encourages GoJ to assess whether its vertical integration has given NTT the incentive and the ability to discriminate in the supply of access and backhaul products to itself and to third parties. The assessment would also lead to consider the need for more robust safeguards to ensure that the market functions properly.

More generally, the EU urges Japan to carry out a comprehensive review of the rules governing communications and broadcasting in Japan. A reinforcement of competitive safeguards would benefit new entrants, competitive carriers, equipment manufacturers and users.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To assess regularly the efficiency of the safeguards put in place to guarantee that NTT East and West provides interconnection and access according to the principles of transparency, non-discrimination and cost-orientation;

b) To ensure that NTT East and WEST publicizes adjusted reference unbundling offers containing all the information required by competitors to plan and coordinate investments and that any changes in the competitors' network that may be required are reasonable and justified;

c) To assess the need for structural remedies vis-à-vis NTT when other competitive safeguards do not succeed in guaranteeing adequate levels of competition;

d) To further discuss RRD proposals mentioned above at expert level in the context of the EU-Japan Information Society Dialogue.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"The discussions which have taken place confirm the good cooperation between the EU and Japan in the electronic communications sector and that we face many common challenges and try to resolve them guided by similar objectives. Enforcing adequate competitive safeguards, especially in the context of the development of next generation networks, is not an easy task and both parties could benefit from a reinforcement of contacts and exchanges at policy and technical level. We appreciate the willingness of the Japanese authorities to engage in such an exchange, especially in the context of a new edition of the EU-Japan High Level Meeting on Information Society in 2009."

Other relevant dialogue: The EU-Japan Information Society Dialogue (the latest meeting was held in Tokyo on 3 March 2008).

3.2 Market access for telecom terminal equipment

(for further details see the EU RRD proposals of 2 October 2008)

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 technical conditions for access to the mobile telecommunications equipment market in Japan. In particular, the EU is concerned 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 2005 RRD, Blanket licensing and network neutrality first raised and discussed in 2007. The Japanese reply delivered in December 2008 does not remove all EU concerns.

Conformity assessment procedures

The EU would like to reiterate its concerns on the narrow scope of the Japanese revised conformity assessment procedure- self verification of conformity (SVC)- which remains limited to wired telecommunication terminals and a limited part of wireless radio equipment.

The EU, on the basis of its positive experience with Manufacturer's Self-Declaration of Conformity in this area, would encourage the GoJ to extend the scope of SVC to wireless radio equipment, with a similar scope to 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).

Blanket licensing

In the EU, telecommunication operators are under the obligation to connect all radio equipment that complies with the R&TTE Directive. This contributed to avoid the control of the terminal market by operators and to make it more competitive, substantially increasing the amount of terminals marketed outside the control of operators.

The combination of blanket licensing for operators and compulsory licensing for use of wireless terminals 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 (e.g. terminals that could use competing networks such as WiFi or competing applications) will have difficulties to reach the Japanese market. As a result competition in the mobile market in Japan is limited.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To extend the scope of SVC to wireless radio equipment, and to exchange views with the EU on approximation of technical requirements which complements the Mutual Recognition Agreement between EU and Japan in this area;

b) To exchange 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. 2008:

"We note from the Japanese preliminary replies that there has been no progress on our proposal to extend the scope of SVC (Self Verification of Conformity) to wireless radio equipment. Further regulatory convergence between us on conformity assessment should be pursued with the view to allowing manufacturers to place radio equipment on the market without any preliminary intervention by authorities. The EU would see mutual benefit to discuss with Japan on issues such as the impact of blanket licensing on market access for mobile terminal equipment."

4 – Air transport

Highlights: The EU welcomes that the Japanese side agrees to review all the bilateral air agreements concluded with EU Member States to include the principle of EC community designation. It also notes the possibility to review the special budgetary account for airport construction and maintenance. EU operators remain concerned by high costs charged by airport authorities and limited airport capacity for international traffic.

Case history: First raised in 1999, discussed in RRD in 2008. The Japanese reply delivered in December 2008 does not remove all EU concerns.

Background ***(for further details see the EU RRD proposals document of 2 October 2008)***

Japan still remains among the EU's most important partners in the air transport area but EU-Japan air traffic relations are still not being exploited to their full potential.

The EU welcomes that GoJ has started a process of revising bilateral air services agreements with EU Member States so as to include the principle of Community designation. The Record of Consultations signed in January 2009 between the Directorate-General for Energy and Transport (DG TREN) of the European Commission and the Japanese Ministry of Land, Infrastructure, Transport and Tourism sets out a road-map for completing the process of restoring legal certainty to all bilateral air services agreements between Japan and EU Member States. The EU hopes this process can be completed shortly.

On this basis, the EU wishes to enhance cooperation in other areas of mutual interest including in relation to safety, security, air traffic management as set out in the Record of Consultations.

The EU is following with interest the efforts of the Japanese government to further liberalise its air transport sector. It notes progress, for example, with respect to the air filing system.

However, in spite of progress made so far, a number of the regulatory and infrastructural issues mentioned in earlier EU RRD proposals still remain to be adequately addressed. It is hoped that the encouraging signs of emerging liberalisation of the Japan's aviation sector coupled with the expansion of the two main airports in Tokyo over the next two years will provide new opportunities and stimulus for EU-Japan aviation relations and for resolving the main outstanding deficiencies.

Particular attention should be given to the following two key issues:

- EU operators remain concerned by high costs charged by airport authorities and limited airport capacity for international traffic. The "airport development special account" is a contributing factor to high airport costs. The EU welcomes the recent announcement by the new Transport Minister about a possible review of the special budgetary account for airport construction and maintenance, in the context of the reform of the Japanese airport management system.

- EU operators are particularly concerned about the apparent lack of a coherent and non-discriminatory plan for an optimal utilisation of existing airport infrastructure. The EU expects that all airport capacity is made available on a non-discriminatory basis, in particular in Tokyo, where capacity is scarce. At Haneda, the currently considered time frame is discriminatory. Non-Asian long-haul flights can only use the airport during night time (22h00-07h00). For EU airlines, this is not attractive as the slots do not allow landings at commercially reasonable times for inbound European flights. It is important that Haneda Airport should be opened up for regular international traffic, including flights to/from Europe, on a non-discriminatory basis. Time restrictions, if any, should be limited to take-off times and not applied to landing times after 18h00.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To complete the process of amending the existing bilateral air services agreements between Japan and EU Member States to include Community designation as a matter of urgency and in a legally binding manner;

b) 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;

c) To allow flights from Europe commercially viable access to Haneda, by removing discriminatory time restrictions and allowing EU carriers access to Haneda at least from 18h00 to 07h00;

d) To abolish the "airport development special account" system allowing to substantially reduce landing, navigation and other user fees charged by airport authorities.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"In recent months, Japan has accepted the principle of Community designation when renegotiating bilateral air services agreements with several EU member states. We take note of GoJ's target to conclude the negotiation with all Member States concerned by mid 2009.

In order to accelerate the process of restoring legal certainty to our aviation relations, we invite Japan to reconsider our proposal for a Horizontal Agreement or – at the very least – an MoU. This would also allow us to move forward quickly in other areas where both Japan and the EU have common interests in closer cooperation.

The EU side hopes that Japan's final written replies will address all of its RRD proposals l from a substantive point of view, including those on distribution, pricing and settlement of airfares."

5 – 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. It encourages Japan to further strengthen its active role in this field. Business context remains difficult for innovative technologies. Appropriate lead-time should be foreseen for the application of the new requirements on pedestrian protection to M1 vehicles of a Gross Vehicle Mass (GVM) of 2,500 kg or more.

The EU welcomes progress regarding the authorization of short-range radar technology to implement automated or semi-automated emergency braking system in the 24 GHz radio frequency band in Japan.

Case history: recurrent issue. Technical guidelines for new safety technologies, including radar technology, first raised and discussed in 2008 RRD. Lead-time for the pedestrian protection requirements first raised in RRD in 2009.

5.1 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 practices, 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 ostensibly 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, however, 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.

While recognising and appreciating the efforts by MLIT to expedite amendment of technical guidelines in a number of specific cases, the EC would welcome if the overall whole framework for drawing up and amending guidelines could be updated to increase transparency and predictability.

Reform proposals

The EU requests the GOJ to consider the following proposals:

a) To establish a transparent procedure for amending of Technical Guidelines, involving foreign stakeholders in the consultation process. GoJ should also set up prescribed timetable for establishing new Technical Guidelines and amending, or demonstrating compliance with, existing Technical Guidelines;

b) To further discuss with EU to define operational ways to improve the procedure for approving new technologies in the short term.

5.2 Use of short-range radar technology

So far, 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 EU welcomes efforts of the Japanese competent authorities MIC and MLIT to reach a balanced decision on access to appropriate radio spectrum for short-range radar, with a view to global harmonization. The EU is confident that the study group can finalize its report with a view to adopting it by end 2009 and that the Japanese regulations and technical guidelines can be amended accordingly by the end of the first quarter of 2010.

Reform proposals

The EU requests the GOJ to consider the following proposals:

To amend the Japanese regulations, including the Technical Guidelines for Safety Technologies, to allow the use of radar technology, once discussions with European business on the appropriate radio spectrum bands for short-range have been finalized. The EU expects a positive outcome by the end of the first quarter of 2010.

5.3 New requirements on Pedestrian Leg Protection

Japan intends to apply the requirements of the Global Technical Regulation (GTR) on pedestrian protection concerning the leg form test to M1 vehicles (passenger cars - new models) with a seating capacity of 9 persons or less regardless of GVM. This new rule is envisaged to enter into force on 24 February 2013 and for new vehicles on 24 February 2018.

Under European Community Regulation (EC) No 78/2009 on the type-approval of motor vehicles (protection of pedestrians and other vulnerable road users), requirements on pedestrian leg protection in line with those set out in the above-mentioned GTR will be applied to M1 vehicles of GVM 2,500 kg or more as from 24 February 2015 on new types of vehicle and as from 24 August 2019 on new vehicles.

The lead-time proposed by the GOJ appears too short for the implementation of technical requirements which imply a re-design of the front end of vehicles.

Reform proposals

The EU requests the GoJ to consider the following proposal:

The EU requests the GOJ to consider the issue in view of finding an appropriate solution with respect to imported vehicles.

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

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"With regard to acceptance of UNECE certificates, we noted explanations from the Japanese side that no additional documentation is requested from manufacturers in cases where the E-Marking is correctly affixed (except in a very limited number of cases, where vehicles are expected to have non-approved equipment).

Regarding procedures for revision of technical guidelines, we proposed further contacts to identify best practices in order to reduce unnecessary administrative burdens.

Regarding Urea SCR [Selective Catalytic Reduction] vehicles, we understand that discussions with manufacturers are ongoing in order to establish a new test procedure which would permit the use of copper in Urea SCR catalysts.

Regarding use of short-range radar (SRR) for safety features [e.g. anti-collision systems], we note that ongoing discussions seem to favour the use of 24GHz radio frequency band. We would encourage such a decision and are pleased that Japan is open to further expert discussions with the EU on this matter."

6 – Healthcare and cosmetics

6.1 Pharmaceuticals

Highlights: The EU notes the recent confirmation of GoJ's policy goals to encourage the development and diffusion of innovative drug medicines with the view to eliminating "the drug lag" in Japan (Cabinet decision of 3 December 2008 for FY 2009 budget formulation and Cabinet Decision of June 2009/ Basic Policies).

It is essential that the competent Japanese authorities pursue a constructive and comprehensive dialogue with industry representatives. When reviewing and reforming the healthcare sector, a comprehensive and balanced approach is necessary to take into account aspects like innovation, shortened drug approval times, adequate rewards for innovation as well as budgetary and public health issues.

Case history: raised in 1999, last discussed in 2008 RRD. The Japanese reply delivered in December 2008 does not remove all EU concerns.

Clinical trials, registration and review of new drug applications

The EU encourages GoJ to further streamline the drug evaluation and approval process in Japan, reduce the time needed for processing New Drug Applications and review the content of the consultation for clinical trials. The EU notes GoJ's efforts toward international harmonization of regulations and the actions taken to improve the processing capacity/capability of the Pharmaceuticals and Medical Devices Agency (PMDA). However, European industry is still asking for improvement in these areas.

The EU is confident that PMDA will implement its action plan to increase by 236 the number of reviewers by end FY 2009 and double the number of reviewers by 2011. It is also keen to see the realisation of the target approval review time foreseen by the "five year Strategy for the promotion of innovative drugs and medical devices" of April 2007.

As regards the PMDA, concerns are voiced about whether the increased fees are justified in relation to the drug assessment and services rendered.

Protection of intellectual property rights

The EU would like to recall its RRD proposal asking for the application of a data protection of 8 years to new combination drugs, drugs for new indications and drugs with new administration routes. This would align with the period of protection given to drugs with new active ingredients. 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 (see further details in the 2008 October EU RRD proposals document).

The EU would like to continue to share its experience with the GoJ in this field.

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; reduce the waiting time for drug clinical consultations; ensure that the fees for drug approval are appropriate and reflect the services rendered; and continue to provide data on average drug application processing time.

To this end, the Ministry of Health, Labour and Welfare should ensure that the processing capacity/capability of PMDA will further strengthened with the view to achieving the targets defined by the "five year Strategy for the promotion of innovative drugs and medical devices" of April 2007" and the latest GoJ's policy developments ;

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. 2008:

"We welcome GoJ's efforts to bring down the drug lag and invite it to further progress on our recurrent RRD concerns, in particular about the length of the review process for new drug applications."

6.2 Vaccines

Highlights: The EU welcomes GoJ's priority policy goal "supporting vaccine development and calling for a production system which can significantly shorten the production time against a new type of influenza" ("2009 Basic Policies" document adopted by a Cabinet decision of June 2009). The EU encourages GoJ to pursue the regulatory reforms necessary to align the Japanese approval procedure for vaccines with international standards and best practices. Greater transparency and predictability as well as a better incentive system for innovative products are key issues.

Case history: first raised and discussed in 2008. The Japanese reply delivered in December 2008 does not remove all EU concerns.

Background

The Japanese vaccine market remains insufficiently open to high-quality and competitive foreign products. The EU supports the regulatory review initiated in 2008 by the Japanese Ministry of Health, Labour and Welfare (MHLW) to update the pre-clinical

and clinical guidelines necessary for vaccine approval. It appreciates that the cooperation between EU and Japanese competent Authorities has been strengthened in this field.

The EU also notes GoJ's willingness to review technical specifications such as the "minimum requirements for biological products" (MRBP), which at present is an area of major concerns for EU industry. It is confident that the "Japanese MHLW research group", which has been tasked to review "MRBP" by FY 2010, will conduct its work to align Japanese MBRP with international standards and practices.

The EU also welcomes MHLW' s initiative to maintain a regular expert dialogue with business, including with the European Federation of Pharmaceutical Industries and Associations (EFPIA), in the ongoing process of reviewing the Japanese approval procedure for vaccines.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To ensure that the legislation and forthcoming guidelines on approval procedures for vaccines are transparent, non-discriminatory and fully aligned with international practices, in particular with WHO and the EU. As a first step, the EU encourages GoJ to finalise the review of non-clinical, clinical and adjuvant guidelines for vaccine evaluation, development and approval for an effective implementation in FY 2010;

b) To update and align the "MRBP" (minimum requirements for biological products) necessary for the clinical development, manufacturing and quality control of vaccines on the basis of international standards and best practices.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"We support GoJ efforts to reduce the "vaccine gap" for innovative products.

The EU welcomes the GoJ's commitment to continue the study group on drafting updated harmonized guidelines for vaccines and involve stakeholders, including foreign business, in this process.

We request GoJ to ensure that European companies can fully participate in the pre-pandemic and pandemic flu preparedness plan, and underline the need of progress in updating and aligning Japanese specifications on the basis of international standards and best practices."

6.3 Medical devices

Highlights: The EU notes that the medical device sector remains a priority sector for regulatory reforms in GoJ's policy goals for FY 2009 (Basic Policies document of June 2009). It welcomes the adoption of reform programs in line with the Shimada Report on FDI of May 2008, such as the Action Program for acceleration of medical devices Review

of December 2008, which was devised by MHLW, as well as the International Strategic Plan and the Mid-Term Plan, published by the Japan Pharmaceuticals and Medical Devices Agency (PMDA) in March 2009. In particular, it notes the PMDA's targets for review performance for medical devices set up in the Mid-Term plan.

Further progress is still needed from Japan to fully align with ISO international standards, in particular ISO 13485 and 14155.

The pricing and reimbursement related issues, which remain key issues, will be addressed in parallel to the RRD.

Case history: First raised in 2003, last discussed in RRD in 2008. The Japanese reply delivered in December 2008 does not remove all of EU concerns.

Background

Globally, the European industry remains concerned by the complex and costly regulatory environment in Japan, including issues related to technical standards, conformity assessment and pricing/reimbursement system.

International harmonisation

a) Global Harmonisation Task force

The EU is pleased to see GoJ continuing to play an active role in the global regulatory harmonisation activities, such as the Global Harmonization Task Force (GHTF), and implementing GHTF's recommendations.

The EU welcomes particularly the following general targets set up in the International Strategic Plan of the PMDA

> *"1. Strengthening of cooperation and building of collaborative relations with the United States (US), the European Union (EU), Asian countries, and relevant international organizations [emphasis added]*
>
> *2. Proactive participation in international harmonization activities and further contributions to such activities*
>
> *3. Improvement and strengthening of information provision to overseas countries".*

b) *International standards*

While taking into account Japanese active involvement in international harmonisation, the EU regrets that MHLW's guidance on good manufacturing practices (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, including in the fields of conformity assessment and quality management system audits (QMS).

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.

Confidentiality arrangement

The Ministry of Health, Labour and Welfare of Japan and the services of the European Commission (Directorate-General for Enterprise and Industry) have recognised the need to further cooperate in the field of regulations for medical devices. A confidentiality arrangement has been drafted. Follow-up is now awaited from the Japanese side. The European Commission would like to invite GoJ to clarify the present situation and inform it of a possible calendar for the signature.

Approval process

The EU recognized GoJ's efforts in 2008 and spring 2009 to streamline the approval process and make it more efficient with a view to achieving the policy goal of eliminating "device-lag" in Japan. In particular, it has noted an increase in medical device review staff in the Office of Medical Devices and strengthened transparency on the performance of PMDA. The EU welcomes the targets of performance review announced in the Mid-term plan and hopes that these targets will be achieved before 2013.

The EU welcomes the dialogue underway between PMDA and industry, including European Industry, in the context of the joint working-level practical task force on medical devices. It is important that regulatory reforms be pursued to reduce the significant delays and difficulties faced by EU companies, in particular as regards the acceptance of foreign clinical data and other technical data which have been already accepted by the conformity assessment bodies and regulators in Europe and the United States.

Innovative health technologies

Many health technologies are characterised by short product life-cycle and high innovation rate. Therefore, the EU would also like to reiterate the importance of ensuring that pricing and reimbursement policies are supportive of the innovation process and provide proper incentives to 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:

a) To eliminate the "medical device lag" and promote innovative technology in Japan. To this end, to further improve the transparency and efficiency of the approval procedure for new medical devices, including by reducing the time period for approval process, by ensuring that the fees reflect the services rendered and by providing data on average review time for new medical devices. On the latter, the EU encourages PMDA to publish timely and periodic reports on its progress towards achieving its performance goals;

b) Given that significant differences remain between JIS and ISO standards, particularly in quality management system (QMS) and good clinical practices (GCP), the EU reiterates it request that Japan fully aligns its QMS and GCP's requirements on medical devices with international standards (ISO and IEC standards), without additional national requirements;

c) To review the Japanese QMS audits procedures to improve their efficiency and streamline unnecessary administrative practices. This issue should be discussed within the context of the joint task-force with Industry and include the issue of "package application";

d) The EU welcomes the ongoing discussions between the MHLW and industry, in the joint working-level practical task force on medical devices, including on IVDs. It considers that work on the following issues should be finalised as soon as possible with a view to defining the necessary administrative guidance regarding implementation: e.g. the actions needed in case of a partial or minor change in a previously approved device, the "bundling" of related products with a view to submitting a single application, when a de novo clinical trial is necessary, the stability and accelerating ageing testing methods;

e) The EU would like to encourage GoJ to continue to actively participate in GHTF's activities. It appeals for a greater coordination in the field of Unique Device Identifiers among the GHTF members;

f) To clarify the underway process conducted in Japan to sign the confidentiality arrangement, including the timing schedule envisaged. It is important that the Ministry of Health, Labour and Welfare of Japan signs this arrangement as soon as possible.

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

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"We would like the GoJ to accept clinical and technical data generated under international standards without further requirements and invite the GoJ to pursue regulatory reforms to eliminate the medical devices lag. The EU looks forward to being informed in due time on the Action Plan for reducing the medical device's gap which will published shortly."

6.4 Cosmetics

Highlights: Since 11 March 2009, no animal testing for cosmetic purposes is allowed in the EU. The EU invites Japan to clarify its commitment towards regulatory acceptance of alternative methods.

Case history: Recurrent issue. Last discussed in 2008 RRD. While the Japanese reply delivered in December 2008 confirmed GoJ's commitment to support the ICATM work, it does not remove all EU concerns.

Background

Animal testing – trade in cosmetics

Since 11 March 2009, a testing ban on animals of ingredients or combination of ingredients has been applied, irrespective of whether or not alternative methods are available. Marketing of finished cosmetic products, as well as of ingredients included in cosmetic products, tested on animals has also been effectively prohibited in the European Community ("marketing ban") for all human health effects with the exception of three test endpoints. For these endpoints the cut-off date is March 2013 and the European Commission will reassess the situation in 2011. The marketing ban also applies to imports.

Alternatives to animal testing are of crucial importance. The EU welcomes the increasing cooperation on international harmonisation of alternative test methods where Japan is also one key player. The "Memorandum of Cooperation" of 27 April 2009 establishing a framework for "International Cooperation on Alternative Test Methods" ("ICATM")[5] under the ICCR ("International Cooperation Cosmetic Regulation") is an important step in this regard.

The EU welcomes the active participation of the Japanese Center for the Validation of Alternative Methods (JaCVAM) in "ICATM" as well as the confirmation of the GoJ's support of JacVAM's activities.

The ICCR-3 meeting, held in Tokyo mid September 2009, has further strengthened cooperation in this field: the EU and JacVAM in particular have committed to continue to accept alternative test methods in their respective regulatory systems. In this context, participants also agreed to draw up a White Paper on Regulatory Acceptance procedures in each of the ICCR jurisdictions.

The EU welcomes the Japanese involvement in research into alternative methods, as demonstrated also in the recent VII World Congress on Alternatives and Animal Use in the Life Sciences in Rome in September 2009.

Against this background, the EU considers that ongoing and intensified cooperation at the validation stage, in ICCR and bilaterally with Japan, is of key importance. Coherent validation will contribute to avoid possible divergence of views at the validation stage and facilitate coherent regulatory acceptance.

In this context, the EU strongly encourages GoJ to recognise EU-accepted alternative methods in case of concrete requests from European industry (see Japanese reply to the 2008 EU RRD proposal).

5 The memorandum of cooperation related to "ICTAM" agreement promotes enhanced international cooperation and coordination on the scientific validation of non- and reduced-animal toxicity testing methods. Representatives from four international agencies – including the European Centre for the Validation of Alternative Methods (ECVAM) and Japanese Center for the Validation of Alternative Methods – JaCVAM - have signed this memorandum.

Confidentiality Arrangement

The Japanese Ministry of Health, Labour and Welfare of Japan (MHLW) and the services of the European Commission (Directorate-General for Enterprise and Industry) have recognised the need to further cooperate in the field of regulations of cosmetic products with a view to maintaining a high level of health protection and safety. This would supplement the important cooperation already achieved in the framework of the International Cooperation on Cosmetic Regulation (ICCR).

A draft "Confidentiality arrangement", taking the form of an exchange of letters, has been prepared. The European Commission would like to invite GoJ to clarify the present situation and inform it of a possible calendar for the signature.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To implement a concrete strategy for the regulatory acceptance of alternative methods in order to replace animal testing in relation to cosmetic products;

b) To recognize EU-accepted alternative methods in case of concrete requests from industry, informing the EU of any possible concern;

c) To cooperate in the drawing-up of a White Paper on Regulatory Acceptance procedures in each of the ICCR jurisdictions, as agreed in ICCR-3 and to continue the positive cooperation at the validation stage through the ICATM framework;

d) To clarify the process underway in Japan to sign the confidentiality arrangement, including the timing schedule envisaged. It is important that the Ministry of Health, Labour and Welfare of Japan signs this arrangement as soon as possible.

Other relevant dialogue: forthcoming confidentiality arrangement between the European Commission services and the Japanese Ministry of Health Labour and Welfare.

7– Food safety and agricultural products

Highlights: The EU would like to pinpoint seven areas of regulatory concerns and/or possible further expert cooperation. The issues of the list of non-quarantine pests and breeders' rights will not be addressed in this 2009 edition of the EU RRD proposals.

7.1 Food additives and flavourings

Highlights: The EU considers it essential that Japan fulfils its commitment of 2002 to complete without additional delay its assessment of the list of 46 priority food additives. In this regard, new working methods which guarantee a speedier and more efficient approval procedure should be explored and applied in the short term. Scientific evaluations carried out by the international standards bodies should be taken into account by Japan to a larger extent.

Case history: First raised in 2000, last discussed in 2008 RRD. The Japanese reply delivered in December 2008 has not removed EU concerns.

Background

Many food additives of worldwide common use, which are 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. Given the resulting negative trade impact for EU exports of food products, the European Commission has consistently and repeatedly asked the Japanese authorities to accelerate the authorisation procedures, especially for food additives widely used worldwide, but not yet allowed for use in Japan. It has also requested Japan to align to a greater extent with international standards, especially those adopted by Codex Alimentarius/ JECFA.

In 2002, the EU and Japan agreed on a list of 46 priority additives that the Japanese Government would have to process at an accelerated pace. Based on information available in early September 2009, a total of 27 additives have been approved, but the authorisation of the remaining 19 additives is still pending.

The EU remains strongly concerned about the excessively slow path of the review process conducted by the Ministry of Health, Labour and Welfare (MHLW) and by indications that insufficient resources have been allocated for this task. Therefore, the EU would like to request Japan to revise its working methods to guarantee a more efficient approval process.

In the RRD 2008 edition, the EU recalled that the approval of the 46 top priority substances should not be considered to be the end of the process, but rather a first step towards the harmonisation of the Japanese legislation on food additives with

international standards, in accordance with the provisions of the WTO SPS Agreement. The EU regrets that no progress has been noted so far in this area.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To complete within one year the authorisation process for the 19 remaining food additives jointly agreed by the EU and Japan in 2002. To this end, the EU invites Japan to take all necessary measures, including new working methods and increased resources, to effectively accelerate and finally complete the approval of the EU list of 46 food additives and substances. It is important in this regard that a smooth coordination between all the Japanese competent administrations/agencies be guaranteed in the short term;

b) More generally, the EU encourages Japan to further streamline its authorisation process for food additives to make it more efficient;

c) To align to a greater extent with international standards as adopted by international bodies such as Codex Alimentarius/ JECFA;

d) To hold a meeting in the short term, e.g. in Tokyo, between the Food Safety Commission and the MHLW on one hand and the EU on the other hand with a view to improving mutual understanding as well as sharing experience and best practices.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"Despite some progress this year, almost half of the substances on priority list from 2002 remain to be evaluated. The EU calls Japan to accelerate and complete the process as soon as possible. In our proposals, we called for this to be completed by the end of 2009."

7.2 Imports of bovine products

Highlights: Despite international recommendations of the World Organisation for Animal Health (OIE), Japan has not yet lifted its bovine spongiform encephalopathy (BSE) related restrictions - dating from the 1990s - against EU imports of beef and beef products. (OIE has classified 25 Member States as countries either as "negligible" or "controlled risk", similarly to Japan which was classified as "controlled risk" country in May 2009). The EU strongly requests the GoJ to fully align its national risk assessment policy and legislation on the OIE's guidelines, including the latest developments, and to ensure that its trade rules for beef are fair, transparent and non-discriminatory.

Case history: First raised in 2005, last discussed in 2008 RRD. Slow progress has been registered for some Member State applications. The Japanese reply delivered in December 2008 does not remove the overall EU concern.

Background

The World Organisation for Animal Health (OIE) has drawn up special recommendations on conditions under which trade in beef and other bovine products should continue. OIE has also officially recognized the sanitary status of countries as regards BSE risk and, in May 2009, accepted that all de-boned meat should be considered as safe. These are important developments in this area.

The EU notes that Japan has resumed imports of beef from the USA and Canada. These countries, according to the OIE categorisation, also fall under "controlled risk". In view of these measures, the EU would like to reiterate that the import ban imposed by Japan on beef and certain other bovine products from the EU is unjustified, discriminatory and not in line with the WTO SPS Agreement.

For many years, Japan has been evaluating the applications from Member States individually. Overall, the process has been excessively slow and cumbersome. During the March 2009 EU-Japan RRD meeting held in Brussels, the EU reiterated its concerns that the Japanese procedures appear considerably less transparent than the EU's own approval and inspection practices and about unnecessary delays in Japan's risk assessment process.

In the 2008 RRD edition, the EU specifically requested Japan to proceed rapidly with inspections to Member States. It welcomes the Japanese delegation's commitment to come for inspections to those Member States which had fully replied to the third round of questionnaires, after being processed more than five years (bilateral meeting of 22 June 2009 held in the margins of the WTO SPS Committee in Geneva). This was confirmed by a letter of 28 August 2009 from the Directorate-General of Trade to MAFF, MHLW and MOFA.

During the March 2009 RRD meeting, the Japanese side invited the EU to point out to which extent the Japanese questionnaires could be improved to make them less cumbersome. In end August, the Commission has informed the competent Ministries of examples of issues which would make the whole process less excessively burdensome for EU Member States. For example, the Commission highlighted that GoJ should request information about BSE-related legislation only once, as it is the same for all Member States.

Despite efforts made so far by Japan, the EU remains concerned by the excessively slow Japanese procedure on EU beef import. It requests that Japan finalises the applications of all Member States without further delays to finally allow imports of bovine meat from the EU.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To accelerate its review process to allow for an early lifting of the existing ban on EU beef;

b) To guarantee a fair and non-discriminatory treatment to all Member States, taking into account also the most favourable treatment accorded to beef imports from other countries classified as " controlled risk" by the OIE;

c) To ensure that all EU Member States' applications for importation of beef and bovine products into Japan are duly processed without administrative delay. The EU understands that the first inspection mission foreseen by Japan in two Member States will take place in Autumn 2009 as agreed by Japan in June 2009. The EU invites Japan to complete the assessments after inspections as quickly as possible. The EU encourages Japan to accelerate the process as regards the other EU Member States and to ensure that the necessary resources will be available to complete the process without further delay;

d) To fully align its legislation with OIE's guidelines on trade in beef and bovine products.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"The EU would like to stress that Japan is not in accordance with the WTO SPS Agreement by not following the international standards, by being clearly discriminatory between WTO members where the same conditions prevail and not being transparent in the risk approval procedure.

Japan should speed up the process, finalise the on-going risk assessments as requested by the Member States, and perform the inspection missions to the Member States during the first half of the year 2009.

Both sides would surely win, if reciprocity would be applied in this area."

7.3 Regionalisation

Highlights: The EU has regularly requested Japan to approve regionalisation (especially for Avian Influenza) based on zoning (as laid down in the EU legislation). Due to the fact that Japan applies the regionalisation only for administrative units rather than geographical areas (zones), this leads to unnecessary import restrictions regarding poultry products from the EU to Japan.

Case history: First raised in 1999, discussed in 2008 RRD. The Japanese reply delivered in December 2008 does not remove EU concerns.

Background

The EU has regularly requested Japan to establish an agreement on the process for recognition of "regionalisation" as regards products imported from EU countries. Bilateral negotiations and evaluations between Member States and GoJ are frequently cumbersome and slow.

The EU is concerned that Japan applies regionalisation for Avian Influenza in a discriminatory and non-scientific way since the affected areas delimited on Japanese territory are dramatically smaller than those delimited on Member States' territory. The EU requests that Japan takes due account of EU legal decisions on regionalisation of an outbreak of a notifiable disease in the European Community. The EU would like to recall that geographical areas in the same country or in adjacent countries, which have the same animal health status and similar disease control systems in place, can be considered as a zone. The EU has applied this definition in the recognition of zones free of certain diseases, infected zones and areas of high or low disease prevalence for both within the EU and in relation to third countries.

Contrary to the Japanese regulatory approach, the EU legislation and its application are fully in line with OIE's international standards and recommendations and can guarantee the most stringent animal health requirements.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To discuss at expert level on regionalisation (especially on Avian Influenza) with a view to improving mutual understanding on each side's regulatory approach and implementing measures. A technical meeting involving EU and Japanese competent experts could be organised within the next six months, e.g. via a videoconference;

b) In line with OIE international standards and recommendations, to recognise the EU regionalisation decisions (especially for Avian Influenza) when applying import measures on products from the EU.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"There are still basic differences between Japan and the EU in the concept of the areas for which regionalization should be applied. The Member States and EU see limited progress in this field. It would be beneficial for both Parties if the new standard procedure were applied so as to increase transparency and so that cooperation and discussions on principles of regionalisation between Japan and the EU will continue in good spirit and confidence and lead to mutually satisfactory solutions."

7.4 Phytosanitary Regulations

Highlights: EU is pleased to note an open dialogue on discussing EU concerns related to phytosanitary regulations. However, obstacles to the import of a wide range of fruit and vegetables from the EU still exist. An increased collaboration between the GoJ, the EU and its Member States when establishing new import requirements for fruit and vegetables is necessary.

The issue of the list of non-quarantine pests will not be addressed in the 2009 edition of the EU RRD proposals.

Case history: First raised in 1999, last discussed in 2008 RRD. The Japanese reply delivered in December 2008 has not removed all EU concerns.

Background

Access to the Japanese market for fresh fruit and vegetables

The EU would like to remind Japan that in the Tokyo 2007 RRD meeting it gave assurances of upcoming progress as regards the 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).

So far, the imports of oranges of "tarocco" variety to Japan have been authorised due to agreement of a protocol recognizing the effectiveness of cold treatment. However, the Japanese authorities have recently asked to test the effectiveness of cold treatment with regard to other varieties of orange, like "moro" and "sanguinello", for which the application of similar specific protocol had been requested. This contrasts with the stated Japanese intention of assimilating similar kinds of fruit in the framework of the same protocol.

The EU would also like to note that although imports of artichokes, asparagus, truffles, mushrooms, chicory, lettuce, pistachios and almonds are authorised at present, this is not case for small fruits (blueberries and raspberries), spinach and onions, which are still subject to Japanese inspection and quarantine.

Reform proposals

The EU requests the GoJ to consider the following proposals:

To apply the protocols already agreed by Japan for certain fruit to other varieties of the same fruit as well as to consider the application of protocols to vegetables. To ensure that the administrative process is smoothly conducted in a fair and transparent manner.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"EU welcomes the openness from Japanese side to show openness in applying measures whose effectiveness has already been approved for one variety of fruit to other variety of the same fruit.

Japan should speed up the progress regarding the two remaining organisms to be added to the list of non-quarantine organisms."

7.5 Requirements for Listeria monocytogenes

Highlights: The EU notes a different regulatory approach between the EU and Japan on how to monitor and control the food-borne bacterium *Listeria monocytogenes* between the EU and Japan. It is important that Japan aligns its regulations with the Codex Alimentarius's international standard.

Case history: First raised and discussed in RRD 2008. The Japanese reply delivered in December 2008 expressed some openness regarding the EU proposals.

Background

The EU shares with the GoJ similar goals to maintain a high level of public health protection, and to ensure that the risks of food-borne illnesses are reduced to an acceptable level. The EU has been implementing severe measures on high-risk food, including strict controls for those types of food which can support the growth of Listeria. However, taking into account the latest scientific evaluations, the EU has set for such foods a limit of below 100 cfu/g whereas Japan's approach remains based on zero-tolerance across the board.

The EU legislation is fully in line with the international standards as agreed in the Codex Alimentarius meeting in June 2009.

During the 2008 RRD discussions, the Japanese Ministry of Health Labour and Welfare (MHLW), showed openness to reflect and consider the possibility to change the Japanese limits. The EU notes the recent interest of the Japanese authorities and their proposal for a study visit in some European countries. The EU considers it a promising step for a future cooperation, including by way of exchanging information and best practices on this matter.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To amend the Japanese regulations and introduce the advanced and internationally and scientifically recognised regulatory approach according to the Codex Alimentarius standard;

b) To share experience and best practice with the EU in this field. As a first step, a video conference could be organised within six months as well other relevant

cooperation activities leading to a better mutual understanding as regards the legislation and the inspection system.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"We appreciate the openness of Japan to consider reviewing in the near future the regulatory approach to limits set for *Listeria monocytogenes,* following international developments."

7.6 Origin labelling for ingredients in processed food

Highlights: In August 2009, a GoJ advisory committee finalised its report on origin labelling for ingredients in processed food. It proposed a system that limits the ingredients that need to be labelled as well as the number of processed foods to which such legislation should apply.

The newly established Consumers Affairs Agency (CAA) is now responsible for a decision on this matter. The EU encourages the CAA to take into account the practical difficulties of ensuring the origin labelling of all ingredients.

Case history: raised in 2008 RRD. The Japanese reply delivered in December 2008 does not remove all EU concerns.

Advisory committee on origin labelling

Former Prime Minister Fukuda instructed the Cabinet Office in November 2007 to re-examine consumer policy in Japan. A number of food-safety scandals accelerated this re-examination and brought food safety to the core of this examination. The Citizens' Life Consultative Committee was established within the Cabinet Office. A draft was presented in March 2009 to the Prime Minister, but the draft did not make any decisions on new labelling requirements. The final report was published in August 2009.

In this process, the Delegation of the European Commission and the European Business Council submitted position papers arguing for a voluntary system. Furthermore, discussions between Commission and Japanese experts took place by video conference in Spring 2009.

Mandatory labelling of country of origin for ingredients

EU legislation stipulates a voluntary system for country of origin labelling of ingredients. Mandatory labelling presents a number of practical difficulties, both for domestic and foreign producers: (a) if a product is made from a large number of ingredients from many countries, there may not be enough space on the label or the label may become illegible, (b) depending on harvest, price etc. the source of ingredients can change at any given moment for legitimate business reasons - it is not practical to change the label each time sourcing changes. (c) Sometimes an ingredient is sourced from more than one country. In the production plant, these products are usually not kept separate.

In this context, it is difficult to tell with certainty where the ingredient comes from for purposes of origin labelling.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To continue discussion with major trading partners on the consequences of mandatory origin labelling for raw ingredients of all processed food;

b) To ensure that any legislation on origin labelling of ingredients stipulates a voluntary system based on a common standard for those who volunteer to label such origin.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"We invite GoJ to keep us informed about the state of discussions on labeling and import requirements for food".

7.7 Organic food certification

Highlights: No progress noted so far on making the equivalency granted in 2001 by Japan to the EU organic production rules and inspection system work satisfactorily. In particular, only 15 of the 27 EU countries are listed by Japan for equivalency. EU Embassies are required to re-certify EU organic products imported into Japan. The use of JAS logo (Japanese agricultural standards) requires a re-labelling in Japan or recourse to an EU certifying body accredited by Japan.

Case history: First raised in 2005, last discussed in 2008 RRD. The Japanese reply delivered in December 2008 does not remove EU concerns.

Background

The EU remains strongly concerned about the cost and administrative difficulties of importing organic products into Japan, including for European certifying bodies interested in the Japanese market or already registered under a previous Japanese registration process. The costs and the onerous administrative procedures imposed undermine the benefits of the equivalency recognised by Japan in 2001.

The EU would like to highlight the three following major concerns:

a) While having recognized the EU as a region with equivalent standards and conformity assessment procedures for organic production to the JAS system, Japan has so far not extended the recognition of equivalency to the 12 new Member States

that joined the EU in May 2004 and in January 2007. This creates a discriminatory treatment among EU Member States which apply the same standards and procedures.

b) Imports of organic products into Japan from the EU have to be accompanied by a "supplementary organic certificate" delivered by EU Embassies, which is not required from other countries for which equivalency has been recognised, such as Australia.

Indeed, each consignment of organic products imported into Japan has to be accompanied by a "transaction certificate" to be issued by governmental agencies or semi-governmental organisations of the country from which the product is originating to certify the conformity of the product to the organic rules of that country. Consequently, Japan does not recognise the EU-approved (private) certification bodies which certify EU organic products, and requires a supplementary certificate from the Embassies.

According to the internationally accepted Codex Alimentarius Guidelines, a "transaction certificate" for import purpose can be issued by designated bodies (in the EU, private certification bodies designated by and under the supervision of the Member States' competent authorities for organic production).

The supplementary certificate delivered by EU Embassies replicates information already contained in the usual invoice documents. Business considers it an additional and unnecessary administrative burden.

c) Japan's restrictive use of the organic JAS logo remains a concern: the right to use the logo is still conditional on a certification by a registered certification body (RCB) that has been approved by the Japanese authorities. This additional specific accreditation is also required for the EU-approved certification bodies even though the EU system has been recognized as equivalent to the Japanese system.

(In contrast, on the EU market, any foreign operator whose organic products were certified according to rules recognised as equivalent to the EU system may use the EU logo. No intervention by a certification body is required, and the operator's right to use the logo is not subject to any further approval or registration procedures. In practice, the EU logo can already by affixed prior to export, at the stage of packaging in the third country's warehouses. This same possibility is not currently available for EU organic products exported to Japan, despite the supposed recognition of equivalence).

Taking into account the advanced process of recognition of equivalence by the EU of the Japanese system for organic production, the EU calls on GoJ to fundamentally reconsider the restrictive and administratively burdensome manner in which it implements the equivalency of EU organic production rules and inspection system recognised in 2001. The EU is strongly concerned that lawfully produced organic products from the EU cannot be exported and freely traded on the Japanese market without incurring additional costs and undergoing redundant administrative procedures.

It also regrets that the European certifying bodies cannot authorise the official Japanese labelling required for the Japanese market.

Reform proposals

The EU requests the GoJ to consider the following proposals:

a) To eliminate discrimination between EU Member States by extending the equivalency granted to the EU as a region equally to the EU countries having joined the European Union in May 2004 and January 2007. The EU invites Japan to take the necessary legal and administrative steps in the short term;

b) To accept the transaction certificate issued by the EU certification bodies as a sufficient guarantee of the integrity of the EU organic products, in line with the the Codex Alimentarius Guidelines. Therefore, GoJ would have to remove the obligation to submit the "supplementary certificate", which creates unnecessary administrative burdens and financial costs;

c) To grant the EU organic products a full market access, including the use of the Japanese logo when packaging in the EU. To this end, Japan would have to recognise the "EU approved certifying bodies" as bodies entitled to certify - in the EU - the EU organic products to be exported to Japan, including for the purposes of labelling with the JAS logo.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"(…) 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."

8 – Wood standards

Highlights: No progress has been noted 2008 concerning the EU RRD proposals.

Case history: first raised in 2003, last discussed in RRD in 2008. The Japanese reply delivered in December 2008 does not remove all EU concerns. The issue of formaldehyde emissions from building materials is first raised in RRD.

Background ***(for further details see the EU RRD proposals document of 2 October 2008)***

Upon updated survey, the EU operators continue to face four main categories of restricted market access:

1) Upgrading European White Spruce in JAS

European White Spruce is classified only as "spruce" in Japan and hence put in JAS category E, second to lowest, when graded according to the Japanese visual grading rules, whereas its real quality and strength properties merit a much higher classification.

2) Recognition of CE marking for structural lumber and glu-lam under the Japanese Building Standards' Law (BSL)
In order to conform with the relevant structural and safety requirements of the Building Standard Law (BSL) of Japan, EU structural lumber (sawnwood) exported there needs to meet JAS and JIS specifications and be marked as such. Alternatively, it can be tested and marked according to the requirements of the West Coast Lumber Inspection Bureau (WCLIB) of North America, whose marking is recognised and accepted in Japan. Under these arrangements, European exporters need JAS or WCLIB marking to sell lumber, mostly as "2x4" batons. European standards and CE marking for structural lumber are not yet recognised in Japan, whereas their recognition and acceptance would facilitate export both administratively and financially.

Similarly to the structural lumber case, European Manufacturers of glu-lams need JAS certification to sell to the Japanese Market, leading to unnecessary costs and administrative burdens for EU exporters.

3) Acceptance of EU fire-endurance tests for wooden building elements
Current GoJ arrangements for fire-endurance tests and fire regulations restrict the import of innovative, large-scale wooden products from Europe (e.g. in-fill wall units) and hence are hindering the spread of large-scale construction in wood in Japan. In particular, the 3+1 hour testing method inherently disfavours wooden material.

Changing the testing method would be key in creating a more flexible regime. It is important that the Japanese fire-endurance test be aligned with ISO standards. The EU would like to recall its proposal of setting up jointly with the Japanese side a technical

working group of experts from industry to discuss the principles and elaborate mutually acceptable alternative solutions to meet valid safety concerns.

4) Formaldehyde emissions from building materials

The Japanese building code "Building Standard Law" stated on 1st July 2003 that all building materials used indoors must emit only low levels of formaldehyde and must be tested for formaldehyde emissions. MLIT (Ministry of Land, Infrastructure and Transport) has developed procedures and standards (JIS) for testing and certifying, with a rating system for formaldehyde release from construction products from F * to F****, the latter being the lowest rating which can be used without any limitations.

European exporting companies can only make applications for export via Japanese agencies or companies and send material to Japan for test and certification. Alternatively, they can use a very limited number of European test institutes using JAS/JIS and recognised by MLIT. Either way, procedures are heavy and costs high.

The Japanese standards are different from the related European and International standards.

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 recognize structural lumbers, Glu-lams and structural panels which have passed EN standards and CE marking as building components which can be put on the market in Japan;

c) 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 2010;

d) To examine ways to simplify the accreditation procedure for testing organisations under the JAS/JIS (Japanese Agricultural/Industrial Standard) and Ministerial Approval Schemes. Internationally accepted data (such as ISO accreditation data) and documentation in English should be accepted in the application to become a JAS-Registered Certification Organisation;

e) With regard to formaldehyde emissions from building materials, to recognize the European formaldehyde testing methods leading to CE marking, or at least the ISO relevant standards should be recognised and allowed for the certification.

EU concluding remarks, RRD High Level Meeting, Tokyo, Dec. 2008:

"The EU underlines the importance of making progress on facilitating market access of EU wooden building materials, products and systems.

The EU side clarified that the idea of establishing a number of technical working groups is intended to make the WBED process more efficient and not to replace it. In view of this explanation, the EU side would encourage GoJ to re-examine its RRD proposals, including on timetable for discussions.
The EU side will prepare a proposal on arrangements for the next WBED meeting after consulting stakeholders."