

**EIGHTH REPORT TO THE LEADERS ON THE  
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE  
July 6, 2009**

The U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) serves as a key bilateral forum for both Governments to promote economic growth through regulatory reform.

The importance of new measures to stimulate growth, open new markets, and improve the business environment has been highlighted in recent months with the sudden downturn in the global economy. Restoration of stable economic growth remains a high priority, and both Governments therefore re-affirm the contributions of the work under this Initiative to achieving this goal as well as helping expand and deepen the U.S.-Japan economic and trade relationship.

Engagement by the Governments of the United States and Japan under this Initiative is two-way, and was launched in the fall of 2008 after an exchange of recommendations by both Governments in October.

Four Working Groups (Cross-sectoral, Medical Devices and Pharmaceuticals, Telecommunications, and Information Technologies) met to address reform in key sectors and areas such as intellectual property, distribution and customs procedures, competition policy, trade and investment-related measures, government procurement, consular affairs, medical devices and pharmaceuticals, commercial law, privatization of public entities, and telecommunications/communications. A High-Level Officials Group also met in May 2009 to advance progress on a range of issues raised under this Initiative.

Following the Working Group and High-Level meetings, this Report to the Leaders was prepared to record progress and detail measures to be taken in the future that respond to each Government's recommendations. This is the eighth annual Report under this Initiative.

In addition to bilateral issues, the Report highlights continuing work by both Governments to strengthen intellectual property rights protection and enforcement in the region and around the world. The two Governments affirm their determination to continue to increase this cooperation in bilateral, regional, and multilateral fora.

Both the Governments of the United States and Japan reaffirm their determination to further promote regulatory reform and, upon the request of either Government, will meet at mutually convenient times to address the measures contained in this Report.

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**REGULATORY REFORM AND OTHER MEASURES BY  
THE GOVERNMENT OF JAPAN**

**I. COMMUNICATIONS**

**A. Promotion of Competition**

1. In February 2009, with a view towards ensuring an environment for fair competition in the telecommunications market, the Ministry of Internal Affairs and Communications (MIC) consulted the Information and Communications Council requesting it to develop recommendations on interconnection rules in response to changes in the telecommunications market environment. Specifically, MIC asked the Council to focus on four main areas:
  - a. ensuring an environment for fair competition in the mobile market including evaluation of the effectiveness of the Category II Designated Telecommunications Facilities System (specific regulation for certain mobile networks);
  - b. ensuring an environment for fair competition in the fixed-line broadband market;
  - c. ensuring an environment for fair competition that promotes new market entrants in the telecommunications platform and content distribution markets including opening up telecommunications platform functions and strengthening dispute settlement functions; and
  - d. interconnection rules in the context of fixed-mobile convergence including consideration of a Bill & Keep mechanism.

**B. Fixed Interconnection**

1. In July 2008, MIC revised ordinances to designate Next-Generation Networks of NTT East and West as Category I Designated Telecommunications Facilities, the consequence of which is an obligation to ensure cost-oriented and non-discriminatory interconnection with competing carriers. In November 2008, based on the revision to the ordinances, MIC authorized the interconnection tariffs of NTT East and West, including network information such as interface conditions necessary for interconnection to Next-Generation Networks of NTT East and West. In March 2009, based on the revision to the ordinance, MIC authorized Next Generation Networks interconnection rates of NTT East and West for FY2009. As a result, for the termination of VoIP on NTT East's network (Hikari Denwa), the interconnection rates was set at 5.69 yen per 3 minutes, and for the termination of VoIP on NTT West's network (Hikari Denwa), the interconnection rates was set at 6.29 yen per 3 minutes.

2. In July 2008, following the launch of the Next-Generation Network services of NTT East and West, MIC revised the public notice to make it obligatory to disclose information on facilities exempted from the Scheme for Providing Network Functions such as facilities for Next-Generation Network of NTT East and West. Accordingly, information on such facilities, including facilities for Next-Generation Network of NTT East and West, must be disclosed, in principle, 90 days prior to the scheduled service launch of the additional functions, so as to enable competitive carriers to consider, in advance, offering services using the additional functions.
- C. **Mobile Interconnection:** The interconnection rate of NTT DOCOMO has been reduced over the last 10 years, and as a result, this rate has fallen to the low end of rates among developed countries using the Calling Party Pays system. In March 2009, MIC was notified that the average interconnection rate between the rate within the same NTT DOCOMO service area and the rate for a subscriber located in a distant NTT DOCOMO service area, was revised to 9.8 yen per minute, a decrease of 11 percent compared to the previous fiscal year.
- D. **Promotion of Advanced Technologies and Services**
1. In order to reallocate specific radio spectrum smoothly and steadily based on the results of surveys on actual radio spectrum usage, MIC developed the “Action Plan for Radio Spectrum Reallocation” in FY2004, and has since revised it annually. In November 2008, MIC announced the revised “Action Plan for Radio Spectrum Reallocation” based on the latest results of survey on actual radio spectrum usage. The revised “Action Plan” includes specific measures, such as to study the efficient use of spectrum to be vacated in the transition to digital TV broadcasting, for the purpose of telecommunications services from July 25, 2012, on the basis of progress in radio spectrum reallocation in the 800/900MHz band, and taking into consideration demand and technological trends of mobile phone systems.
  2. In December 2008, the Information and Communications Council reported Technical Requirements for the 3.9-generation mobile communications systems reflecting efficient use of frequencies and preventing interference. In April 2009, MIC enacted license policy and other regulations for introduction of 3.9-generation mobile communications systems. MIC received applications submitted by EMOBILE Ltd., NTT DOCOMO, INC., SOFTBANK MOBILE Corp. and KDDI Corporation / Okinawa Cellular Telephone Company. In June 2009, MIC approved all four establishment plans.
  3. In June 2009, the Broadcasting System Committee of the Information and Communications Technology subcommittee of the Information and Communications Council, examining broadcasting systems appropriate for portions of VHF band, released for public comment the draft report on technical

requirements for multimedia broadcasting system for mobile terminals.

- E. **Multilateral Affairs:** The Government of Japan and the Government of the United States will continue to participate in the discussion at the ITU on the issue of network externality premium, with a view to ensuring consistency with other international agreements.

## II. INFORMATION TECHNOLOGIES

### A. Health Information Technology

1. The New Grand Design (Grand Design for the Use of Information Technologies in the Medical Services, Healthcare, Nursing and Social Welfare) sets out policies and plans for a five year period, considering the future vision of enhanced IT utilization. The Ministry of Health, Labor and Welfare (MHLW) will continue to make its best efforts to ensure technology neutrality and interoperability in health IT.
2. MHLW has established reimbursements, concerning telemedicine, for remote diagnostic imaging technologies. MHLW will continue to consider reimbursement systems for the use of IT in the medical field, if there are technologies that become candidates for health insurance applicability, upon inspection of data based on scientific grounds concerning the efficacy and safety of the technology.
3. The United States initiated the Integrating the Healthcare Enterprise (IHE) approach that promotes the integration of systems with components from different vendors by ensuring interoperability through the combination of international standards. MHLW has supported this approach since FY2007.

The Ministry of Economy, Trade and Industry (METI) has implemented, a three-year plan from FY2006 to FY2008, with projects to ensure interoperability between hospitals in Nagoya for stroke patients, and in Iwate, Kagawa, Tokyo, and Chiba for perinatal care. Furthermore, as a three-year plan beginning in FY2008, three Ministries, the Ministry of Internal Affairs and Communications (MIC), MHLW, and METI, are implementing the Personal Health Record (PHR) Project to facilitate the collection and storage of lifetime personal health information aimed towards effective utilization for health promotion. Standardization is an important issue in all of these projects. In each project, METI is promoting standardization in conjunction with the International Standards Organization, and is moving the projects forward so that they are fully compliant with international standards. METI will post the reports of the projects on its website (in Japanese).

4. The Government of Japan is making various efforts to provide the public with information about government supported projects by posting such information on

the websites of each Ministry. METI posted information on its website about procurement for the PHR Project, in which METI is cooperating closely with MHLW and MIC.

5. The Government of Japan will continue to provide meaningful opportunities for interested parties, including the private sector, to present their views on health IT proposals, policies and rules, and participate in relevant health IT working groups and advisory panels.
6. MHLW is continuously making efforts to ensure the technology neutrality of health IT by proposing the implementation of HL7 and DICOM, which are international standards, as a standard rule for exchanging medical information using health IT in Japan.

## **B. IT-Related Financial Reform**

1. The Payment and Settlement Working Group (the Working Group) was established under the Second Subcommittee of the Financial System Council in May 2008. The Working Group examined the institutional framework of payment services by holding informational sessions with the service providers and other relevant parties. Based upon discussions in the Working Group, the Second Subcommittee of the Financial System Council published its report titled “The Institutional Arrangements for Payment Services - Promoting Innovation and Protecting Users” in January 2009. In accordance with the report, the Financial Services Agency (FSA) drafted the “Payment Services Bill” (the Bill) and submitted the Bill to the Diet on March 6, 2009. The Bill was enacted on June 17, 2009. The “Payment Services Act” (the Act) provides that non-banking entities will be allowed to provide fund transfer services without a banking license provided such entities are registered by the Prime Minister. The Act also provides that the registered service providers will be required to reserve funds equal to or greater than the amount which the service providers are obliged to transfer for their customers, and to secure these funds in the event of the service providers’ bankruptcy.
2. The FSA continues to make efforts to collaborate with the private sector. In light of the opinions expressed by interested parties in the Financial System Council and other advisory groups, legislation and regulations related to the financial market are discussed before they are deliberated and enacted by the Diet. Furthermore, the public comment procedure pursuant to the Administrative Procedure Act is requisite for developing cabinet orders and cabinet office ordinances. The FSA has developed and will continue to develop legislation and regulations taking into account compatibility with international practice.
3. The FSA continues to coordinate with IT Strategic Headquarters (ITSH) in compiling the Priority Policy Program based on the Basic Act on the Formation of an Advanced Information and Telecommunications Network Society, and other

plans. In enacting the Electronically Recorded Monetary Claims Act, the FSA submitted the bill jointly with the Ministry of Justice, and is making efforts to ensure that its policies are consistent with Japan's other regulations and policies by inviting relevant government agencies to act as observers to the Financial System Council as needed.

### C. **Government IT Procurement Reform**

1. Increasing Transparency: The Cabinet Secretariat conducted a follow-up survey on implementation of the "Basic Policy for the Public Procurement of Computer Systems" (Basic Policy), and published the results on its website in January 2009. To ensure greater transparency and fairness of procurement procedures and realize a truly competitive environment in public procurement, the Ministry of Internal Affairs and Communications (MIC) upgraded the database system for information systems of public procurement cases. The system includes new contents such as procurement plans, specification documents and tender notice information, and has been in operation since April 2009. At the launch of the system, MIC requested ministries to enter their cases into the database in a proper and timely manner. When ministries conduct procurement related to large-scale information systems projects, the Basic Policy requires that the specification documents are checked for clarity and fairness in accordance with the Basic Policy by their CIO advisers including external experts.
2. Expanding Japan's Buy-Dole System: In order to encourage ministries to implement the April 2007 amendment to the Industrial Technology Enhancement Act, the Ministry of Economy, Trade and Industry instituted the "Guideline for the Japanese Buy-Dole Act related to Software" in August 2007. The Guideline clarifies the rights and obligations of vendors. While the Japanese Buy-Dole Act does not compel each ministry to allow contractors to own the rights to intellectual property they develop through government-sponsored programs, METI will keep requesting that each ministry apply the Guideline to their procurements.
3. Limiting Vendor Liability: To clarify the scope of vendor liability, the Basic Policy identifies points to consider in making a contract, such as writing an agreement related to changing specifications and setting the scope of liability in damages. MIC will continue to encourage ministries to clarify the scope of vendor liability.
4. Banning Backdating: The Government of Japan will enforce the Basic Policy's prohibition of the backdating of contracts. MIC operates an office that can receive complaints about backdating of contracts and will follow up by contacting relevant ministries.
5. Expanding Use of Competitive-Bidding Rules: In August 2007, Japan's Cabinet decided that incorporated administrative agencies should, in principle, engage in

competitive bidding. All of them have developed action plans on their use of competitive bidding, and are making efforts to reduce the number of non-competitive contracts. In July 2008, the results of the implementation review of such action plans were published.

6. Employing “Best-Value” Principles: Government of Japan procurement authorities, when appropriate, may conduct IT procurement using the overall-greatest-value evaluation method which awards the winner by evaluating all factors of the proposals including price, performance, function and technological capability.

D. **Privacy**: In June 2007, the Quality-of-Life Policy Council (the Council) issued its “Summary of Opinions on the Protection of Personal Information” (Summary) for its review of the effectiveness of the Act on the Protection of Personal Information (Privacy Act), emphasizing a future consideration of potential measures to improve implementation, and a desire to curb overreactions to the Privacy Act.

1. A Subcommittee under the Council emphasized in the Summary that the Government of Japan should take necessary measures for the standardization of various implementation guidelines. In light of this opinion, in July 2008, the Cabinet Office presented its proposal for the standardization of the 37 guidelines in 24 sectors (as of April 1, 2008) to promote the protection of personal information with the goal of integration and consistency throughout Government. Each ministry and agency agreed to review its own guidelines for consistency with the standardized guidelines by the end of July 2009. The Government of Japan will encourage ministries and agencies to follow the standardized guidelines.
2. Having considered the conclusions reached in the Summary, in April 2008, the Government of Japan partially revised the Basic Policy on the Protection of Personal Information. In light of the revision, the Government of Japan implemented measures such as public relations activities to curb overreaction. For example, the Cabinet Office held explanatory sessions on the Privacy Act in all 47 prefectures that were attended by approximately 12,000 people, and produced leaflets and a video on the Privacy Act for the prevention of overreaction. The Government of Japan is determined to continue similar measures in 2009.
3. The Governments of Japan and the United States share the view that it is important to provide effective protection for individuals’ personal information while ensuring efficient cross-border data flows. In recognition of these principles, and the value of a flexible privacy approach, the Governments of the United States and Japan will continue to participate in multilateral fora such as the Organisation for Economic Co-operation and Development (OECD) and Asia-Pacific Economic Cooperation (APEC) to exchange information and generate consensus on issues such as privacy.

## E. **IT and e-Commerce Policymaking**

1. Considering Private Sector Input: The Government of Japan understands that it is important to seek and consider opinions from the private sector at all stages of policy making and facilitate private sector participation in government-commissioned IT and e-Commerce advisory bodies. IT Strategic Headquarters (ITSH) and the Expert Committee on IT Strategy Evaluation include many members from the private sector, who propose and implement IT strategies. In addition, the Government of Japan has sought various opinions from the private sector, both from within and outside of Japan, by employing public comment procedures. The Administrative Procedure Act stipulates that the period for submission of comments set pursuant to the provision of the Act shall be 30 days or more from the date of public notice.
2. Promoting Technology Neutrality: The Government of Japan recognizes that it is important to develop standards that promote technology neutrality. The Government of Japan will continue to cooperate closely with the private sector in international standards development activities and promote a competitive market environment by implementing necessary laws, regulations, and guidelines.
3. Improving Implementation of Rulemaking: The Government of Japan understands that it is important to enforce reasonable periods between the publication of final versions of IT and e-commerce regulations and their effective dates and to publicize the implementation dates well in advance. The Government of Japan, when establishing, revising, or abolishing laws and/or guidelines regarding regulations, will continue to give full consideration to their influence on interested parties, by means such as collecting public comments regarding the substance and/or effective date of such changes.

## F. **Strengthening the Protection and Enforcement of Intellectual Property Rights**

1. Strengthen Enforcement Against Copyright Infringement:
  - a. *Downloading of Content from Infringing Sources*: The Government of Japan submitted a bill to the Diet to amend the Copyright Law which makes clear that the private use exception does not apply in the case of a download of a musical work or a motion picture from an infringing source with the knowledge that the source is infringing. It passed the Diet on June 12, 2009. The Government of Japan will consider the issue of copyrighted works other than music and motion pictures within the Council for Cultural Affairs this year. The Government of Japan will continue to discuss with interested parties further measures in a timely manner to address the above issue.
  - b. *Online Piracy*: The Government of Japan exchanged information

concerning its legal system with the Government of the United States. The Government of Japan explained its preventive measures against online infringement, under the Provider Liability Limitation Law. The Government of Japan is studying the legal implications of measures to more effectively prevent unauthorized online distribution of pirated materials.

- c. *Ex officio*: The Government of Japan considered whether the requirement of a complaint from an injured party for prosecution of copyright crimes under the Copyright Law should be modified. In the report in January 2009, which reviewed the deliberations of the Council for Cultural Affairs, the Council reconfirmed its position that careful consideration is necessary regarding the provision of *ex officio* authority to competent authorities, and reaffirmed that the requirement of the right holders' complaint for prosecution of copyright crimes does not constitute a serious obstacle to investigation. The Government of Japan notes the Government of the United States' view that *ex officio* authority is an important tool for facilitating effective investigation and prosecution of copyright crimes.

2. Statutory Modernization:

- a. *Technical Protection Measures*: The Government of Japan will continue its information gathering on civil and criminal remedies for unauthorized circumvention of technological protection measures, including access controls, and all forms of trafficking in circumvention devices or services. The Government of Japan will continue to update the Government of the United States on these efforts.
- b. *Copyright Term Extension*: Within the Council for Cultural Affairs, the Government of Japan will continue its deliberations in a timely manner on extending the terms of protection for copyrighted works, with consideration of relevant factors including global trends and the balance between right holders' and users' benefits, and will provide the United States updates on its deliberative process. The Government of Japan notes the Government of the United States' recommendation that all copyrighted works receive the same term of protection as currently provided for cinematographic works in Japan.
- c. *Statutory Damages*: In discussions within the Council for Cultural Affairs, the Government of Japan considered whether it is necessary to establish a pre-set statutory compensation system for infringement in order to decrease the burden on right holders. In the report in January 2009, the Council for Cultural Affairs concluded that there are no particular difficulties in proving the amount of damages under the current law (e.g. Article 114-5 of the Copyright Law), and also that it is necessary to consider whether any statutory damage regime would be consistent with

other legal provisions such as the Civil Law and the Intellectual Property Law. The Government of Japan notes the Government of the United States' view that the availability of statutory damages is an important tool for compensating right holders and deterring infringement.

3. Proposed Limitations or Exceptions to Copyright Protections and Other Copyright Related Recommendations: Regarding new limitations, exceptions, or the expansion of existing exceptions to copyright protections and other copyright related recommendations by committees involved in drafting copyright related recommendations, including committees within the Agency for Cultural Affairs, the Government of Japan invites comments from the general public and an exchange of opinions with right holders in formulating the recommendations. In addition, these committees invite relevant right holders as commissioners, and have opportunities to hear right holders' opinions as necessary in the process of discussion. The Government of Japan continues to make effort to provide meaningful and timely opportunities for both domestic and foreign right holders to participate in and contribute to the deliberations on copyright related recommendations.
4. Patent Procedures:
  - a. *Deferred Examination System*: The Government of Japan's patent examination system allows the Patent Office to focus its examination resources on requested applications by allowing unrequested applications to drop out. Upon patent examination request, the Government of Japan also makes efforts to provide the result of first office action as quickly as possible, so that information of search and examination results can be utilized by other offices.
  - b. *Patent Application Prosecution*: In a patent application prosecution, each patent application is examined in line with the examination guideline which provides that, in principle, all of the reasons for refusal should be notified in the first office action.
  - c. *Grace Period*: The Government of Japan will continue to discuss with the Government of the United States the issue of a 12-month grace period within multi-national fora as part of a patent harmonization package.
5. Transparency Regarding Other Initiatives: The Government of Japan invites public opinions in the process of promoting initiatives affecting the application of copyright. Besides, the Government of Japan exchanges opinions with stakeholders both in Japan and abroad. Councils and workshops permit the participation of the stakeholders in discussions as members and/or observers, as appropriate. The Government of Japan also continuously endeavors to maintain transparency regarding other initiatives.

**G. Strengthening U.S.-Japan Cooperation on IPR Protection and Enforcement**

1. The Government of Japan and the Government of the United States continue to strengthen cooperation on intellectual property rights on a bilateral and multilateral basis.
2. In particular, regarding cooperation on intellectual property rights in the Asia-Pacific region, some concrete outcomes have been achieved including the Asia Pacific Economic Cooperation (APEC) Anti-Counterfeiting and Piracy Initiative, the formulation of six-model guidelines based on the above mentioned Initiative, and the development of the APEC Cooperation Initiative on Patent Acquisition Procedures.
3. In addition, the two governments have worked closely to launch negotiations for an Anti-Counterfeiting Trade Agreement (ACTA) as a U.S.-Japan joint initiative. The close cooperation continues as the negotiations move forward.
4. Bilateral cooperation continues in various ways including the conclusion of the 2008 Statement of Cooperation towards work-sharing and international harmonization of patent systems between the offices of both governments.
5. However, there still remain international challenges with the protection of intellectual property rights to which both governments need to respond concertedly.
6. Both Governments will continuously strengthen cooperation regarding the formulation and implementation of international rules on intellectual property rights both domestically and internationally.

### **III. MEDICAL DEVICES AND PHARMACEUTICALS**

- A. **Input in Healthcare System Changes:** When the Ministry of Health, Labour and Welfare (MHLW) and its advisory bodies such as *Chuikyo* consider and implement changes in Japan's health care system, members of industry, including U.S. industry may express their views to MHLW, which MHLW will take into consideration. MHLW has been taking measures to enhance the global competitiveness of its healthcare industry as the country positions the pharmaceutical and medical device industries to be key drivers of Japan's future industrial growth. The New Pharmaceutical Industry Vision is aimed at eliminating the drug lag, developing an internationally competitive drug industry, and making Japan an attractive investment destination. In addition, the Five-Year Strategy for Development of Innovative Pharmaceuticals and Medical Devices proposed measures such as properly evaluating innovative products.
- B. **Medical Device and Pharmaceutical Pricing Reform and Related Issues**
  1. Pharmaceuticals:

- a. *Kanmin Taiwa*: In the Government-Private Sector Dialogue for Discovery of Innovative Drugs and Medical Devices (*Kanmin Taiwa*) the “5 Year-Strategy on Innovative Drugs and Medical Devices” includes efforts for the appropriate assessment of innovative products in relation to the pricing system. MHLW will continue to fully consider ideas that industry, including U.S. industry, presents at *Kanmin Taiwa*.
- b. *Chuikyo Expert Member*: MHLW will continue to select suitable candidates, irrespective of nationality, to serve as expert members of the Drug Pricing Expert Subcommittee of *Chuikyo*.
- c. *Pricing Reform Proposals*: In the drug pricing system revision of 2008, MHLW has further enhanced the evaluation of innovativeness of new drugs by taking measures such as 1) increasing the range of premium rates in the similar efficacy comparison method; and 2) revising the cost accounting method to reflect the level of innovativeness as well as efficacy and safety. The system proposed by industry, including U.S. industry, includes measures to: 1) provide initial prices reflecting levels of innovation; 2) maintain drug prices for reimbursement during patent or reexamination periods; and 3) promote generics. These three points are important parts of the current pricing reform discussion. Industry’s proposals were discussed four times between July 2008 and March 2009 in the Drug Pricing Expert Subcommittee of *Chuikyo* and will continue to be discussed, considering the views of those involved.
- d. *Annual Price Revisions*: MHLW notes that the Government of the United States urges the Government of Japan to avoid implementing a system by which prices of pharmaceuticals and medical devices can be reduced annually under Japan’s medical care insurance system. MHLW will continue to provide industry with opportunities to discuss annual price revisions.
- e. *Repricing Based on Market Expansion*: MHLW notes that the Government of the United States continues to urge the Government of Japan to abolish or avoid further expansion of Japan’s market-expansion repricing rule. MHLW will continue to discuss with industry, including U.S. industry, the issue of repricing based on market expansion.
- f. *Foreign Price Adjustment (FPA) Rule*: MHLW will continue to discuss with industry, including U.S. industry, the issue of the FPA.
- g. *Drug Price Premiums*: Drug price premiums are intended to recognize the level of clinical innovation. MHLW will flexibly apply the range of premium rates based on the applicability of new drugs to the premiums.
- h. *Prescription Period for New Drugs*: MHLW notes industry’s proposals

regarding the prescription period for new drugs and is open to discuss those proposals.

- i. *Vaccines*: MHLW will continue to discuss with industry, including U.S. industry, the issue of vaccines in the medical care insurance system.

2. Medical Devices:

- a. *Foreign Average Price (FAP) Rule for Medical Devices*: The FAP rule has reduced price differences of 126 functional categories since it was implemented in 2002. In the medical device pricing revision of 2008, MHLW reduced the functional categories affected, used only industry-supplied data on the four comparator countries, maintained a maximum price cut of 25 percent, and decided to phase in the cuts. Considering public interest in foreign price differences, MHLW will continue to provide industry, including U.S. industry, with opportunities to express its view on the FAP rule, including the impact of foreign exchange fluctuation, and will consider those views as necessary.
- b. *R-zone*: MHLW recognizes the unique nature of medical devices and the importance of innovation in the medical technology sector. Issues related to the R-Zone will be discussed at *Chuikyo* (Subcommittee) with opportunity for industry, including U.S. industry, to express its views.
- c. *Evaluation of Innovation*: In the medical device pricing revision of 2008, MHLW made several revisions, such as raising the reimbursement price adjustment premiums of new and revised medical materials, and establishing a new improvement premium by integrating the effective premiums in order to strengthen the incentives for their development and practical application. In furtherance of this progress, MHLW will also provide U.S. industry opportunities to express its view on the cost of doing business in Japan. Considering the differences in the basic function between drugs and medical materials, MHLW will continue discussions on premiums towards the next medical device pricing revision.
- d. *Speedier Introduction of C1/C2 Products*: As for the prompt introduction of reimbursement for medical devices, the listing of products in the C2 category has been made quarterly since the medical device pricing revision of 2006. In 2008, with regard to medical devices classified in the C1 category, MHLW substantially shortened the waiting time for the listing of products. MHLW will continue to discuss proposals from industry, including U.S. industry, on the prompt introduction of reimbursement for medical devices, which will help to reduce the device lag.
- e. *Reimbursement Pricing Process*: MHLW has held hearings with industry,

including U.S. industry, regarding pricing new devices after the medical device pricing revision of 2008. In March 2009, MHLW held a hearing where medical device companies could make a case for why their Special Treatment Materials or capital equipment should receive a higher reimbursement price. In addition, in the medical device pricing revision of 2008, MHLW revised the rule so that reimbursement prices can be increased for medical devices determined to be in extremely short supply. MHLW will continue to consult with industry on the reimbursement pricing process, including that for C2 applications.

- f. *Functional Categories*: In the medical device pricing revision of 2008, MHLW revised the functional categories, such as subdividing the functional categories of clips used for operation of malformed brain vessels and medical materials for home medical care. In addition, between April 2006 and April 2008, MHLW established 15 new functional categories for new devices. MHLW will continue to consider the addition and revision of functional categories for new devices that have certain improved functions over existing products, as necessary.
- g. *Diagnostic Imaging Techniques*: In the medical device pricing revision of 2008, MHLW conducted hearings with industry, including U.S. industry. In the revision, based on the evaluation of the Technical Evaluation Subcommittee of *Chuikyo*, MHLW established new premiums for coronary artery CT and for heart MRI, which academic associations had requested. MHLW will continue to hear industries' views regarding pricing reforms, including those of diagnostic imaging, at *Chuikyo's* Special Treatment Materials Subcommittee.
- h. *In-Vitro Diagnostics (IVDs)*: In March 2009, MHLW held the second IVD study meeting (*benkyokai*) of the year. The meetings have provided industry with valuable opportunities to explain their IVD reimbursement issues to MHLW. MHLW will continue to take part in such meetings. In the 2008 reimbursement revision, MHLW raised the reimbursement fee for "quick testing" in hospitals and other testing fees by considering valuation of such testing. MHLW will continue to provide industry, including U.S. industry, with opportunities to express its views on the IVD issue.

- 3. Blood Products: MHLW will continue to be open for discussions with industry, including U.S. industry, about pricing issues related to blood products.

C. **Medical Device and Pharmaceutical Regulatory Reform and Related Issues**: The Government of Japan is continuing to strive to eliminate the lag in the introduction in Japan of innovative medical devices and pharmaceuticals. The Government of Japan will improve its regulatory system by taking the following actions in FY2009.

1. Pharmaceuticals:

- a. *Development of Pharmaceuticals Including Simultaneous Global Development (SGD):* In considering development plans and data requirements, MHLW and the Pharmaceuticals and Medical Devices Agency (PMDA) will continue to make science-based decisions based on the characteristics of individual products.

The Government of Japan supports simultaneous global development of pharmaceuticals as a means to promote the efficient development of pharmaceuticals in Japan. The Government of Japan has been implementing the “New 5-Year Clinical Trial Activation Plan” since 2007, promoting global clinical trials by taking measures such as: 1) improving the environment in hospitals for clinical trials, including global clinical trials; 2) supporting the efficient implementation of clinical trials to reduce the burden on companies; and 3) publishing guidelines called the “Basic Principles on Global Clinical Trials.” It is anticipated that SGD trials will help to reduce the drug lag. Through various dialogues such as the “Dialogue between the Public and Private Sectors for Innovative Pharmaceuticals and Medical Devices,” MHLW and PMDA will continue to exchange opinions with relevant parties, including U.S. industry.

- b. *Waiting Times for Drug Clinical Trial Consultations:* MHLW and PMDA have made substantial progress in reducing waiting times for drug clinical trial consultations. PMDA abolished the system of arranging appointments on the basis of points, and rearranged the system to respond to all consultations in a timely manner in FY2008. MHLW will continue to support PMDA to meet the demand for clinical trial consultations in a timely manner.
- c. *Drug Review Times:* MHLW will ensure that PMDA implements its plan to increase by 236 the number of drug reviewers by the end of FY2009, and that PMDA redoubles efforts to improve systems for evaluating pharmaceuticals and conducting clinical trial consultations. There were 346 reviewers in PMDA as of April 2009. PMDA is also making efforts in facilitating reviews by conducting organizational reforms, such as the establishment of a new division specializing in anti-cancer drugs. In terms of improving the quality of reviews, PMDA is making efforts to ensure consistency by taking various measures, such as: 1) developing and circulating to new drug reviewers in April 2008 a document that summarizes points to be considered during the actual evaluation process of drugs; and 2) deploying experienced reviewers among each review team. MHLW and PMDA will continue to exchange views with industry, including U.S. industry, to look at process improvements for both consultations and reviews such as introducing a two-track system and improving the efficiency of the question-and-answer component of the

review process.

- d. *Acceptance of Foreign Clinical Data*: PMDA will continue to accept foreign clinical data in accordance with the ICH E5 guideline.
- e. *New Drug Application Approval Processing Times*: MHLW will continue to exchange views with industry, including U.S. industry, on reducing the processing time for new drug applications before issuing final approvals.
- f. *Post-Approval Partial Changes*: MHLW issued a notification on review time of post-approval partial change applications and expressed their intention to make efforts to reduce review times, including setting targets such as six month and twelve month total approval times (in median) depending on characteristics of partial change applications by the end of CY2009 and FY2009, respectively.
- g. *Vaccines*: MHLW is developing guidelines on vaccines in a study group, where industry, including U.S. industry, has participated. The Government of Japan will continue to discuss with industry, including U.S. industry, to improve regulatory reviews of vaccines.

2. Medical Devices:

- a. *Performance Goals and User Fees*: MHLW devised the “Action Program for Acceleration of Medical Device Review” in December 2008 following discussion with industry, including U.S. industry. In accordance with the Action Program, PMDA will measure review times for the approval cohort in median, and for reference PMDA will also measure review times for the submission cohort in median. PMDA will continue to publish this information, enabling industry to evaluate the performance of PMDA. PMDA will work to collect sufficient data that will promote meaningful discussions at semi-annual meetings of regulators and industry to measure progress of the Action Program.
- b. *Medical Device Review Staff*: PMDA increased its staff in the Office of Medical Devices to 47 as of April 2009 on the basis of the Action Program and will continue such increases in accordance with the program goals. To ensure knowledgeable and skillful reviewers, PMDA will create training programs by: 1) promoting personnel exchanges among domestic and foreign universities and research institutions; and 2) referring to U.S. Food and Drug Administration training programs. The progress of the Action Program will be reviewed twice a year in meetings of regulators and industry, including U.S. industry.
- c. *Review Criteria and Class II Devices Eligible for Third Party Review*: In accordance with the Action Program, MHLW continues to work with

industry, including U.S. industry, to clarify review criteria and ensure that all Class II devices will be eligible for third-party review by FY2011 as a matter of principle.

- d. *Partial Change Approvals:* MHLW, PMDA and industry, including U.S. industry, formed a working-level task force to discuss issues related to reviews and approvals. Following discussion in the task force, MHLW issued two notifications about the procedure for partial changes regarding medical devices. The task force will continue to work on a flow chart which helps to clarify the required regulatory procedure for a partial change. Under the pilot program for the real time review process for “special designated changes” mentioned in MHLW’s November 2008 notification, MHLW and PMDA will endeavor to achieve the two month target indicated in the notification.
- e. *Accelerated Stability Test Data:* In September 2008, MHLW issued a notification clarifying accelerated testing as the basis for approval where scientific evidence validates the testing methods. MHLW will continue to work on a question-and-answer notification to increase the understanding of when accelerated stability test data can be used as a basis for approval. Issues related to accelerated stability testing will be discussed at a task-force meeting upon request.
- f. *Bundling of Device Applications:* MHLW and industry, including U.S. industry, agreed to discuss the issue of bundling of device applications, and a new working group was formed under the working-level task force to handle the issue in May 2009. MHLW will continue to work with industry, including U.S. industry, to specify the scope of “one product” and to develop guidelines for bundling of device applications where scientific and regulatory issues can be addressed most efficiently in one review.
- g. *Raw Material Data Requirements:* In order to expedite device reviews, MHLW will streamline the requirements for raw material data in submissions, taking into consideration the nature of medical devices and that certain medical devices present greater risks than others. In addition, MHLW will continue to ensure that Japan’s requirements for biocompatibility testing are fully consistent with ISO 10993. MHLW will continue to work with industry, including U.S. industry, to further streamline the raw material requirements.
- h. *Accreditation of Foreign Manufacturer:* MHLW and PMDA have published instructions for industry on applications for the Accreditation of Foreign Manufacturers both in Japanese and English to encourage industry to make valid applications for prompt processing. MHLW will discuss at the task force meeting with industry, including U.S. industry, their

proposals on further streamlining procedures to obtain the Accreditation of Foreign Manufacturers.

- i. *Factory Inspection Program*: MHLW has been utilizing several fora for discussion with *third-party certification bodies*, industry, local governments and PMDA to create streamlined QMS conformity assessments. MHLW will continue to discuss this issue with these groups.
- j. *In-Vitro Diagnostic (IVD) Approvals*: MHLW plans to issue a notification about stability testing and the effective period of IVDs based on the discussion in the working level task force. MHLW will discuss with industry, including U.S. industry, such as on issues related to pre-approval evaluation by the National Institute of Infectious Diseases. MHLW is open to discussing with industry its proposals regarding IVD regulations including the continuation of clinical performance testing after regulatory application.

#### D. **Blood Products**

1. Communication: MHLW discussed issues related to plasma protein products with industry in FY2008.
2. Labeling: MHLW will continue to provide industry with meaningful opportunities to discuss the labeling of *kenketsu* and *hikenketsu*.
3. Supply and Demand Plan: MHLW has formulated the Supply and Demand Plan to ensure a stable supply of plasma protein products. MHLW will continue to provide industry with meaningful opportunities to discuss the plan and promote a better understanding of the plan.
4. Partial Change Approvals: MHLW and PMDA will exchange views with industry, including U.S. industry, on reducing review times of “partial changes” of blood products.

#### E. **Nutritional Supplements**

1. Regulatory Categories and Claims:
  - a. The nutritional supplement system in Japan is set in accordance with the guidelines of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU). MHLW will continue to make efforts to improve the system for food with health claims based on the outcomes of reviews in the CCNFSDU.
  - b. The nutritional supplement system in Japan is set in accordance with the guidelines of the Codex Committee on Nutrition and Foods for Special

Dietary Uses (CCNFSDU). To ensure fairness and transparency, MHLW will continue to provide appropriate opportunities to inform the industry, including U.S. industry, during the development, revision or implementation of regulations related to nutritional supplements.

- c. MHLW will continue to exchange views with industry, including U.S. industry, on the Japanese health food system, including ways to improve the Foods for Specified Health Uses (FOSHU) system and proposals for a system to allow ingredient-specific health claims that is both transparent and based on scientific principles.
- d. MHLW has been providing the public with information through the National Institute of Health and Nutrition database. MHLW will continue to exchange views broadly with consumers and industry, including U.S. industry.

2. Health Food Safety Regulations:

- a. To ensure fairness and transparency, MHLW will continue to provide appropriate opportunities to inform the industry, including U.S. industry, during the development, revision or implementation of regulations related to health food.
- b. MHLW explained the classification criteria of drugs, foods, and food additives and the process to judge whether ingredients are drugs or not. MHLW will continue to provide opportunities for industry to exchange views and to ask questions about the classification criteria of new ingredients and the application process.

3. Food Additives:

- a. The Government of Japan will continue to accept requests for consultation regarding applications for substances classified in Japan as food additives, including organic solvents, tablet compression lubricants, and alternate chemical forms of nutrients, from industry, including U.S. industry, and to make efforts to designate food additives in the most efficient way possible.
- b. The Government of Japan recognizes the importance of international harmonization in the area of food additives. (Also see section on “Food additives” under Other Government Practices on page 47.)
- c. In the import procedure for food at quarantine stations, hearings are conducted on the origin of food additives at the importer’s request when nonconformity with standards for use of food additives has been suspected. MHLW will continue to make efforts to conduct this procedure in a more efficient and more consistent manner, such as by sharing common

perceptions among quarantine stations and posting reference information on Japanese Government websites.

4. Import Issues:

- a. MHLW will continue its efforts to make import procedures more efficient at quarantine stations, considering opinions from related industries.
- b. MHLW has considered a new scheme in which quarantine stations issue a document with details of consultation to the importer in place of a stamp. This new scheme has been introduced as of July 2009. MHLW will inform the U.S. Government and Japanese importers of the contents of the scheme.
- c. Most manufacturing process of nutritional supplements is carried out by smaller enterprises. The Government of Japan encourages developing new nutritional supplements which utilize local agricultural and fishery products. The Government of Japan will continue to comprehensively address the issue of tariff levels in WTO negotiations including those on nutritional supplements containing the same ingredients as medicaments.

F. **Cosmetics and Quasi-Drugs**

1. Quasi-Drugs:

- a. With regard to product approval standards, MHLW continues to discuss with industry, including U.S. industry, ways to increase the transparency and efficiency of the quasi-drug approval process.
- b. With cooperation from industry, including U.S. industry, MHLW issued a notification about the list of active ingredients approved in previous applications for medicated cosmetics on December 25, 2008. To the extent possible within resource constraints, MHLW will make efforts to update the list.
- c. MHLW continues to exchange opinions concerning quasi-drug regulations, including the evaluation of additives in quasi-drug applications, with industry, including U.S. industry.

2. Advertising and Labeling:

- a. MHLW will continue to work with industry, including U.S. industry, to determine the appropriate labeling of cosmetics on reducing the appearance of fine lines due to dryness with consideration of related information in the United States and EU and will aim to reach a conclusion in a timely manner.

- b. MHLW will continue to exchange opinions on the regulations of claims and effectiveness of cosmetics, including the differences between substantiation of claims in the United States and regulations on cosmetics claims in Japan, with relevant parties, including U.S. industry.
  - c. MHLW believes that advertisements with numerical data for quasi-drugs and cosmetics are not appropriate in current situation. However, MHLW will continue to exchange opinions with industry, including U.S. industry.
  - d. In September 2008, MHLW participated in an information exchange session on advertising regulations in the U.S. and Japan for cosmetics and related products. Other participants included the U.S. Federal Trade Commission, the U.S. Department of Commerce, U.S. industry, and Japanese industry.
3. Other Transparency and Regulatory Issues:
- a. MHLW exchanged opinions with industry, including U.S. industry, at the Local Advertisement Controllers' Meeting (*Rokusyakyō*) in November 2008 and February 2009. MHLW will continue to provide U.S. industry with the same opportunities for participation that it provides to Japanese industry.
  - b. MHLW will devise ways to streamline the import process of cosmetics by the end of FY2009, including streamlining procedures for the Notification of Foreign Manufacturer, and will make efforts to implement any changes in a timely manner. In this regard, MHLW will continue to discuss this issue with industry, including U.S. industry.
  - c. MHLW newly created a homepage for cosmetics and quasi-drugs on MHLW's website. The homepage includes key documents, such as the list of previously approved active ingredients in medicated cosmetics published by MHLW in December 2008. PMDA also posted key documents on its homepage for cosmetics and quasi-drugs. To the extent possible within resource constraints, MHLW will continue to improve its website in terms of publishing regulations and notifications in a timely manner. MHLW will continue to work with industry, including U.S. industry, to provide English translations of key documents and to publish regulatory information.
  - d. In April 2009, MHLW participated in an information exchange session on cosmetics and related products that included developments in U.S. advertising regulations and an overview of the U.S. Cosmetic Ingredients Review. Other participants included the U.S. Federal Trade Commission, the U.S. Department of Commerce, U.S. industry, and Japanese industry.

## IV. FINANCIAL SERVICES

### A. Specific Measures

1. Institutional Investor Disclosure Rules for Large Shareholdings: The Large Shareholdings Disclosure Rules for Institutional Investors were revised in 2006 and the new rules went into effect in January 2007. The Financial Services Agency (FSA) has been continuously monitoring market practices regarding large-shareholding transactions since then and will continue to monitor the situation in the future in consultation with relevant parties.
2. Credit Bureaus:
  - a. The revised Money Lending Business Law calls for the expansion of credit information use and mandatory use of the Credit Bureau by consumer finance companies from the viewpoint of preventing excessive lending. Through the Credit Bureau of various types of consumer finance companies, the Financial Services Agency (FSA) is working to require the availability of full-file credit information in order for firms to assess risks and promote sound credit underwriting on a rigorous, scientific basis as a means of consumer protection and financial system stability, giving due consideration to the protection of personal information.
  - b. Similarly, the revised Installment Sales Act calls for the expansion of credit information use and mandatory use of the Credit Bureau by Credit Purchase Mediator from the viewpoint of preventing excessive credit. Through the Credit Bureau of various types of Credit Purchase Mediator, the Ministry of Economy, Trade and Industry (METI) is working to require the availability of full-file credit information in order for firms to assess risks and promote sound credit underwriting on a rigorous, scientific basis as a means of consumer protection and financial system stability, giving due consideration to the protection of personal information.
  - c. In reviewing the functions of the Credit Bureau System, including financial institutions such as banks, consumer finance companies, Credit Purchase Mediator, first of all, the FSA and METI will monitor developments in the problem of multiple debts.
3. Defined Contribution Pensions: The Government of Japan recognizes the importance of enhancing the defined contribution pension system in terms of a renewed emphasis on securing retirement income and promoting labor mobility.
  - a. Last year, allowing employee contributions to corporate-type defined contribution pensions was included in the Measures to Counter Difficulties in People's Daily Lives, a new set of economic countermeasures formulated by a joint meeting of the Government and

Ruling Parties Council on new Economic Countermeasures and the Ministerial Meeting on Economic Measures. The Government of Japan decided to allow employee contributions to corporate-type defined contribution in the Tax Reform 2009 package, and submitted a bill amending the Defined-Contribution Pension Act, which includes the introduction of such a measure, to Diet in March 2009.

- b. With regard to the tax deductible contribution limits, the following increases were decided in the Tax Reform 2009 package by Cabinet meeting:

(1) Corporate-Type Defined Contribution Pensions:

- i. in the case of having no other corporate pension plans  
46,000 yen/month → 51,000 yen/month
- ii. in the case of having other corporate pensions plans  
23,000 yen/month → 25,500 yen/month

(2) Personal-Type Defined Contribution Pensions:

in the case of having no corporate pension plans  
18,000 yen/month → 23,000 yen/month

The Government of Japan plans to revise the government ordinance of the defined contribution pension in the future.

- c. With regard to early withdrawals from the personal-type defined contribution pension, an amended bill for the unification of Employees' Pension Systems including a relaxation of the requirement for early withdrawals from personal-type defined contribution pensions was submitted in the ordinary Diet session 2007 and is currently under deliberation.
- d. The Ministry of Health, Labour and Welfare, taking into due consideration progress in the enforcement of the various systems and regulations put into place so far, will continue its efforts to improve the defined contribution pension system, in consultation with interested parties.

4. Opt-Out for Customer Information Sharing:

- a. Regarding the revamp of firewalls regulations, a related bill was enacted in June 2008, followed by the revision of relevant Cabinet Orders and Cabinet Office Ordinances, which were promulgated in January 2009. Those statutes came into force June 1, 2009.

- b. In the revision, the FSA eased restrictions on the sharing of undisclosed customer information, based on the viewpoints of enhancing users' convenience and establishing a practical system, in addition to the perspectives of respecting the will of customers and appropriate protection of customer information, as shown below:
  - (1) Allowing the sharing of undisclosed corporate customer information within a group, so long as those corporate customers are explicitly given opportunities to opt out;
  - (2) Making pre-authorization by the FSA for sharing customer information within a group for internal management purpose unnecessary.

The FSA formulated these measures through close dialogues with market participants, including both domestic and foreign financial institutions.

5. Online Financial Services:

- a. The FSA submitted the "Payment Services Bill" (the Bill) to the Diet in March 2009, in order to ensure the appropriate implementation of the payment services, to protect users and to promote supply of the payment services. The Bill was enacted in June 2009.
- b. The "Payment Services Act" (the Act) provides that non-banking entities shall be allowed to provide fund transfer services without a banking license, provided such entities are registered by the Prime Minister. The Act also provides that the registered service providers shall be required to reserve funds equal to or greater than the amount which the service providers are obliged to transfer for their customers, and to secure these funds in the event of the service providers' bankruptcy.
- c. In addition, as for the prepaid payment instrument, both own-issue-business-type issuer and third-party-business-type issuer have been regulated by the Prepaid Certificate Act. And now, having been basically taken over the regulation by the existing Prepaid Certificate Act, the Act provides that not only the prepaid payment instrument upon which the issuer records value, but also the prepaid payment instrument without value-record on it as the issuer records value on a computer server or other objects other than the instrument itself shall be included in the scope of the regulation.

**B. Transparency**

- 1. No-Action Letters and General Inquiries Regarding the Interpretation of Laws and Regulations:

- a. The FSA continues to improve the transparency and predictability of regulatory actions such as the no-action letter system. The FSA's no-action letter system has responded to five inquiries for one year from April 2008.
- b. Moreover, since the FSA has introduced the program for General Inquiries Regarding Interpretation of Laws and Regulations, which will complement the no-action letter system in April 2005, the FSA has responded to two inquiries by way of this program.
- c. The FSA will continue its efforts to enhance use of the no-action letter system and the program for General Inquiries Regarding Interpretation of Laws and Regulations.

2. Provide Written Interpretations of Japan's Financial Laws:

- a. The FSA has been engaged in an initiative to improve the quality of financial regulation (Better Regulation).
- b. One of the pillars of this initiative is to improve the transparency and predictability of regulatory actions. Under this pillar, the FSA publishes and revises the Supervisory Guidelines. In addition, even when an interpretation has not been formally requested, the FSA widely offers its interpretation by publishing reference cases, including Questions and Answers (Q&As). The FSA will continue to assess needs and provide interpretations of Japan's financial laws.

3. Transparency in the Inspections Process:

- a. Both the FSA (Inspection Bureau) and the Executive Bureau of Securities and Exchange Surveillance Commission (SESCEB) have taken measures to enhance the transparency of the inspection process. The FSA published the "Financial Inspection Basic Guidelines," the "Inspection Manuals," and further generated the "Basic Policy and Plan for Financial Inspections," the "Financial Inspection Instruction Samples," and the "Opinion Submittal Samples." Similarly, the SESCEB published the "Basic Guideline for Inspection of Financial Instruments Firms" and the "Inspection Manuals for Financial Instruments Firms," in addition to releasing the "Basic Policy and Plan for Inspection of Financial Instruments Firms" annually and quarterly updates to the "Main Findings in the Inspection of Financial Instruments Firms."
- b. Moreover, the FSA provides the opportunity for exchanges of opinions with financial institutions through the "on-site inspection monitoring," which enables inspected financial institutions to engage in dialogue with

senior back-office officials of the FSA Inspection Bureau and to express their comments directly to the FSA officials without the company of inspectors. The on-site inspection monitoring, which was previously conducted on an ‘upon request’ basis, has been applied to all cases in principle from July 2007. Also, the FSA provides several opportunities for written feedback to inspected financial institutions through “off-site inspection monitoring” prior to and after notification of the inspection result. Furthermore, the FSA introduced an “Opinion Submission System” in which inspected financial institutions could submit their opinions in the case they have any objections to inspectors even after they held thorough discussions with inspectors.

- c. By the same token, financial instruments firms (FIFs) being inspected by the SESCEB are given an opportunity to use the “on-site inspection monitoring” system, which enables the FIF to engage in a direct dialogue with senior officials of the SESCEB back office without the presence of inspectors while the inspection is still in process. The FIF can also express its views to the SESC back office in a written form by using the “off-site inspection monitoring” system within a month after the conclusion of the inspection. Furthermore, the “opinion submission system” allows the FIF to submit its opinions to the SESCEB back office in case it cannot agree with the inspectors’ findings even after thorough discussions.
- d. The FSA and the SESCEB have been making improvements in system arrangements including those mentioned above in order to secure transparency of the inspection process, and will continue to manage the system properly in the context of promoting better regulation. The FSA continues to have opportunities for exchanging views with foreign financial institutions and financial sector industries’ associations in a variety of ways and at various levels, recognizing that the inspection process is a serious concern for institutions and the market. The SESCEB also continues to have opportunities for exchanging opinions with domestic as well as foreign FIFs and their industrial associations to discuss issues surrounding the developments of financial markets and/or identified in on-site inspections. The FSA and the SESCEB will continue to have open communications with financial sector industries as well as their associations.

## **V. COMPETITION POLICY**

### **A. Improving Antimonopoly Compliance and Deterrence**

- 1. Strengthening Measures to Address Hard Core Cartel Violations: The Government of Japan submitted the Antimonopoly Act (AMA) Amendment Bill to the Diet in February 2009. The bill was enacted on June 3, 2009, and most of

its provisions will come into effect within one year after the date of promulgation to be specified in the Cabinet Order implementing the amendments. The amendments include:

- a. a 50 percent increase in the surcharge rate for enterprises that played a leading role in an unreasonable restraint of trade (e.g. an increase of the surcharge from the current 10 percent of sales for all large manufacturing enterprises to 15 percent of sales for large manufacturing enterprises that play a leading role in the conspiracy);
- b. the extension of the statute of limitations for both cease and desist orders and surcharge payment orders from the current three years to five years;
- c. an increase in the maximum prison sentence for criminal violations under Article 89 of the AMA from the current three years to five years, which also results in extending the statute of limitations for such criminal violations to five years; and
- d. a revision to the leniency program to allow two or more enterprises within the same company group, upon certain conditions, to jointly file a leniency application and be assigned the same order of priority.

2. Minimizing Unintended Deterrence of Procompetitive Unilateral Conduct:

- a. The amended AMA subjects to surcharges enterprises that engage in the exclusionary type of private monopolization, or abuse of superior bargaining position. In addition, enterprises that engage in a second offense of certain types of concerted refusal to trade, discriminatory pricing, unjust low price sales and resale price restrictions within a 10-year period will also be subject to surcharges.
- b. The Japan Fair Trade Commission (JFTC) considers it important to ensure transparency and predictability of law enforcement in order to avoid chilling legitimate business conduct caused by the expansion of the scope of conduct subject to surcharges. From this perspective, the amended AMA clarifies the specific requirements for finding an AMA violation for concerted refusal to trade, discriminatory pricing, unjust low price sales, resale price restriction and abuse of superior bargaining position that would be subject to surcharges.
- c. In addition, before the amendments come into effect, JFTC will issue guidelines to clarify the conduct that will constitute the exclusionary type of private monopolization that will be subject to surcharges so that enterprises will know in advance that engaging in specific conduct will subject them to surcharges. JFTC published a draft of the guidelines and solicited public comments in June 2009 and JFTC will consider public

comments, including those of foreign business and legal communities, before finalizing.

3. Eliminating AMA Exemptions:

- a. With regard to the AMA exemption system for air carriers in the international aviation sector, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) established its Study Group on the Optimal System of AMA Exemptions in August 2008 and has been reviewing the optimal system of AMA exemptions for air carriers in the international aviation sector since then. After having heard and considered the views of industry and consumer representatives, among others, the Study Group plans to complete and publish its final report and recommendations within FY 2009. In light of the discussion and recommendations of the Study Group, MLIT intends to reach a conclusion within FY 2009 on whether the AMA exemption should be eliminated or not.
- b. The International Maritime Transport Sub-committee, a special group under the Maritime Affairs Section of the Council for Transport Policy, which is a ministerial advisory body for the MLIT Minister, considered in 2007 whether the AMA exemption for international shipping activities continued to be necessary. After careful consideration, the Council recommended in December 2007 that further consideration be given to this issue from the viewpoint of ensuring a competitive international shipping market while ensuring stable and reliable maritime transport.

Accordingly, MLIT is making further studies on this issue from the following four points of view which were described in the above recommendation:

- (1) the antimonopoly policies taken by other nations and the impact of those policies on the Japanese shipping industry;
- (2) the development of the international shipping market including the emergence of large shipping companies;
- (3) whether the agreements among shipping companies are working for stable supply of the shipping service; and
- (4) the impact of eliminating or continuing the antimonopoly exemption on the Japanese economy.

In conducting this study, MLIT is also analyzing the impact of the abolition in October 2008 of the EU competition law exemption for the liner conference block

on the Japanese shipping economy and the continued utility and appropriateness of the AMA exemption.

4. Improving Pre-Merger Notification Procedures: The amended AMA requires that share acquisitions by corporations be notified to JFTC in advance in the same way as other types of business combinations, such as mergers. The amended AMA also revises the notification thresholds for business combinations, providing that, in principle, the notification threshold shall be based on the total amount of domestic turnover of a corporate group. These revisions are intended to ensure that the AMA's pre-merger notification and review system is consistent with the International Competition Network's "Recommended Practices for Merger Notification Procedures" and OECD's "Recommendation of the Council on Merger Review." More specifically, the notification thresholds for most types of transactions (with some exceptions) will increase from the current 10 billion yen of assets for the acquiring party to 20 billion yen of annual domestic turnover, and from the current 1 billion yen of assets for the acquired party to 5 billion yen of annual domestic turnover.
5. Strengthening JFTC Economic Analysis Capabilities: JFTC has been actively recruiting outside personnel in order to enhance their ability of economic analysis. As of April 1, 2009, seven economists in JFTC are engaged in work that requires economic analysis such as merger reviews and economic research utilizing their expertise. These economists, where necessary, are available to provide advice to various divisions in JFTC regarding economic related issues.

**B. Improving Fairness and Transparency of JFTC Administrative and Investigatory Procedures**

1. Enhancing Hearing Procedure Credibility and Transparency: The Government of Japan is committed to promoting public confidence in and transparency of the JFTC hearing examination system. In this regard:
  - a. A supplementary provision of the law that amends the AMA provides that the Government of Japan shall review the current ex-post hearing examination system in its entirety and carry out consideration within FY2009 from the perspective of ensuring that respondents in JFTC investigatory and enforcement procedures are afforded procedural fairness consistent with fulfillment of the purposes of the AMA. The views of all interested parties submitted to the JFTC, including those from the foreign business and legal communities, will be considered in that review. Based on the results of that consideration, the Government of Japan will take necessary measures within FY2009.
  - b. JFTC will ensure that hearing examiners are qualified and impartial. In that regard:

- (1) Currently, out of seven JFTC hearing examiners, four are legal professionals who are not career JFTC officials. JFTC has ensured and will continue to ensure that the panel of hearing examiners for each public hearing includes at least one of these legal professionals, including by revising its Rules on Hearing or taking other measures.
- (2) The AMA provides that any person who has performed duties of an investigator in a particular case or who has otherwise been involved in the examination of a particular case shall not be designated as a hearing examiner for the said case. In addition, JFTC does not and will continue not to designate a hearing examiner who has a conflict of interests in a particular case to serve as a hearing examiner in the said case. JFTC will revise its Rules on Hearing or take other measures to ensure that hearing examiners with a conflict of interest in a particular matter, including examiners with significant ties to the respondent or to any other person or entity affected by the outcome of that matter, will not be designated as a hearing examiner in that particular case.

2. Increasing Fairness of JFTC Investigatory Processes: JFTC is committed to promoting public confidence and transparency of JFTC investigatory procedures, including through the following policies and measures:
  - a. With regard for procedures to be followed by JFTC investigators in obtaining evidence, JFTC provides documentation that informs the persons concerned of the suspected unlawful conduct and relevant market that is the subject of the investigation, the provision(s) of the AMA suspected of having been violated, and the authority under the AMA to conduct the relevant investigatory process when it conducts an on-site inspection in accordance with the provision of Article 47(1)(iv) of the AMA, or orders, pursuant to the provisions of Article 47(1)(i) of the AMA, persons or enterprises to provide required documentary information to JFTC without conducting an on-site inspection. When JFTC conducts an inspection, search, or seizure in a criminal investigation it will present to the persons concerned the warrant issued by a judge. In the case of criminal investigations, materials which are allowed to be seized by JFTC are limited by the warrant issued by a judge, and in the case of administrative investigation JFTC will only collect materials reasonably related to the alleged specific violation of the AMA.
  - b. As provided in section 18 of the JFTC's Rules on Administrative Investigations, JFTC allows persons who were ordered to submit materials (including pursuant to administrative on-site inspections) to peruse and copy the materials submitted.

- c. JFTC believes that the current system of not allowing attorneys to be present during interrogation of a witness is appropriate, and therefore has no plans to change its current practice in this regard. However, JFTC will continue to allow attorneys representing the subject enterprise to be present during an on-site inspection, and to represent respondents of proposed JFTC orders during the advance notification process and during hearing procedures.
- d. JFTC has undertaken to provide expected recipients of cease and desist orders or surcharge payment orders with approximately two weeks in which to review the evidence JFTC intends to use against them and to present their opinion and submit evidence to JFTC, before JFTC will make a final determination. However JFTC sets the above prior notice and response period appropriately on a case by case basis, taking into account factors such as the time needed for the prior explanation. Based on the JFTC's Rule on Administrative Investigation, which stipulates that the period can be extended by JFTC's authority or at the request of the expected recipients, JFTC has extended and will continue to extend the prior notice and response period when the recipient gives JFTC justifiable grounds for doing so.
- e. JFTC has a procedure that allows any person who has complaints about measures taken by JFTC investigators, such as failing to follow JFTC rules providing for procedural fairness when issuing a submission order of materials, to make a motion of objection to JFTC.
- f. JFTC will by the effective date of the amended AMA stipulate in its Rules on Administrative Investigation procedures concerning issuance of warnings, including procedures that ensure fairness in the issuance of warnings and the publication of the names of warning recipients.
- g. JFTC recognizes the importance of protecting from disclosure confidential information obtained in the course of its investigations. In this regard:
  - (1) JFTC will appropriately treat documents, which contain communications between an attorney and his or her client relating to provision of legal advice sought by the client, in accordance with Article 100 of the National Public Service Act and, if applicable, Article 39 of the AMA, if such documents include confidential information protected by the said provisions, considering that such documents are, in principle, intended to be confidential between an attorney and his or her client, and will allow parties who are under JFTC investigation and believe that such documents of theirs have been seized by JFTC to make a request that particular documents be provided confidential treatment.

- (2) The amended AMA provides authority to JFTC to restrict access to case records by interested parties when it is found that there is a risk of impairment of the interests of a third party or there are other justifiable reasons for such restriction. JFTC will implement this authority so as not to disclose business confidential information if there is a risk of impairment of the interests of a third party or there are other justifiable reasons.

### C. Addressing Bid Rigging

1. Preventing Conflicts of Interests in Procurement: The amended National Public Service Act and relevant laws, which include provisions regarding reemployment of retiring government officials, became effective December 31, 2008. This amendment restricts government officials from seeking jobs with corporations that have business relationships with the officer and brokering employment opportunities for retiring and retired officials, and restricts retired officials from contracting incumbent officials.
2. Improving Efforts to Eliminate Government-Assisted Bid Rigging:
  - a. MIC and MLIT notified local governments in December 2008 that they should give appropriate training to their employees from the view of preventing unlawful activities in violation of the Act on Elimination and Prevention of Involvement in Bid Rigging, etc. (“Kansei Dango Prevention Act”). MIC and MLIT also continue to encourage local governments to establish a third party auditing organ which contributes to monitoring compliance with the Kansei Dango Prevention Act and other relevant laws.
  - b. JFTC is making efforts to educate central and local government officials, as well as officials from government-financed corporations, on the requirements of the Kansei Dango Prevention Act, how to uncover evidence of bid rigging and how to avoid violating that Act, including by organizing several seminars and training workshops. JFTC will continue these efforts in the next Japan Fiscal Year and beyond.
  - c. JFTC continues to actively enforce the provisions of the Kansei Dango Prevention Act. In October 2008, JFTC found that 10 companies engaged in unlawful bid rigging on designated electrical equipment construction projects by agreeing on a designated successful bidder appointed by an employee of the City of Sapporo, and JFTC demanded the Mayor of Sapporo City to take improvement measures necessary to avoid further violations of the Kansei Dango Prevention Act.

3. Expanding Administrative Leniency Programs: Based on the Act for Promoting Proper Tendering and Contracting for Public Works, MLIT, MIC, and MOF conducted a survey on current efforts to implement proper tendering and contracting public works by public procuring entities as of September 1, 2008, and published its result on December 17, 2008. According to the survey results, 70 percent (12 of 18) of State institutions now have adopted the Administrative Leniency program which reduces the period of suspension from bidding for companies admitted into JFTC's Leniency program. According to a later survey, the House of Councillors, the Cabinet Office (partially), National Police Agency, Imperial Household Agency, MOJ, MOFA, MOF, MEXT, MHLW, MAFF, MLIT, Ministry of the Environment, MOD, and the Supreme Court have adopted the above program. Therefore, the total number of State institutions that have adopted an Administrative Leniency program reached 14 as of April 2009. In addition, 90 percent of prefectural governments, 100 percent of designated cities, and 30 percent of municipal governments have implemented administrative leniency programs.
4. Improving Procurement Practices:
  - a. The Government of Japan has been making substantial efforts to improve procurement practices by central government and local governments to realize a reduction in the incidence of bid rigging. For example:
    - (1) The Government of Japan has been promoting the use of the Overall Greatest Value Method for evaluating bids on public works. In that regard, on December 22, 2008, MIC and MLIT issued a notice entitled "Promotion to Conduct Bidding and Contracting in an Appropriate Manner" to encourage local governments to introduce and enhance the Overall Greatest Value Method, in addition to expand it by setting a policy regarding what type of procurement the method will apply to and establishing an annual implementation target rate. As of September 1, 2008, more than 80 percent (15 of 18) of State institutions, 100 percent of prefectures and designated cities, and more than 40 percent of municipalities adopted the Overall Greatest Value Method for public works.
    - (2) MIC and MLIT continue to encourage local governments to further promote proper tendering and contracting for public works, including by implementing the open and competitive bidding system, installing electronic bidding systems and creating a system to deal with complaints about tendering and contracting in a neutral and fair manner. As of result of these efforts, as of September 1, 2008, 100 percent of prefectures and designated cities, and 60.6 percent of municipalities have adopted the open and competitive bidding; 97.9 percent of prefectures, 100 percent

of designated cities, and 21.5 percent of municipalities have installed electronic bidding systems; and 97.9 percent of prefectures, 94.1 percent of designated cities, and 13.4 percent of municipalities have set up a system to deal with complaints about tendering and contracting practices.

- b. With respect to the Whistleblower Protection Act, which took effect in April 2006, the central and local governments have set up whistleblower hotlines for receiving reports from their employees on violation of laws, including bid rigging. As of March 31, 2008, all central and prefectural government entities and 35.5 percent of municipal government entities have established a whistleblower hotline. The Cabinet Office will also continue its effort to raise awareness of the importance of local governments implementing an effective whistle-blowing scheme through various means, including by holding meetings and symposia throughout the country, distributing public relations brochures, running workshops for local government officials, and so on.

## **VI. COMMERCIAL LAW AND LEGAL SYSTEMS REFORM**

### **A. Promoting Cross-Border Mergers and Acquisitions (M&A)**

1. Implementing the Recommendations of the Expert Committee on FDI Promotion:
  - a. In December 2008, the Cabinet Office revised the Program for Acceleration of Foreign Direct Investment in Japan, from the perspective of promoting foreign direct investment. That Program states that the Government of Japan, among other measures, will conduct a study of the current M&A climate in Japan, including the number and value of recent M&A cases, and will disseminate the results of that study widely both domestically and overseas.
  - b. The Government of Japan recognizes that the current provisions of the Companies Act, including triangular mergers, are a positive outcome of regulatory reform. The Government of Japan also recognizes, however, that since its introduction in May 2007, there has been only one cross border triangular merger transaction. The Government of Japan will continue to monitor the use of this technique and to study the reasons for its use or non-use.
2. Exploring Alternative Qualifying Rules for Tax-Deferred M&A Transactions: The Government of Japan will continue to review the effectiveness of the current qualifying rules for tax-deferral in M&A transactions.
3. Protecting Shareholder Interests in Anti-Takeover Measures:

- a. As provided in the Program for Acceleration of Foreign Direct Investment in Japan, the Government of Japan will continue to actively disseminate to Japan's business sector and investors the appropriate use and implementation of takeover defense measures in accordance with the report, "Takeover Defense Measures in Light of Recent Environmental Changes" issued by the Corporate Value Study Group (CVSG) in June 2008.
- b. Although the CVSG Report mentions that a target company is not obligated to set up a special committee composed of outside directors to review acquisition proposals, the Report also states that a company should ensure independence of such outside directors from incumbent management if such a special committee is set up, and that directors are responsible for their decisions even if they follow the opinions of a special committee.
- c. Even though Japan is not at the stage to obligate by legislation the establishment of a special committee composed of outside directors to review acquisition proposals, the Government of Japan will continuously monitor the practice and court rulings with a view to determining whether any further measures are necessary to ensure that the decision-making process on acquisition proposals focuses on the interests of shareholders rather than exclusively on those of management.
- d. In the disclosure system of the Financial Instruments and Exchange Act, which protects investors' interests, a company is required to disclose information about the major shareholders in the Annual Securities Reports and the Extraordinary Reports, and a shareholder, whose possession is above a certain threshold, is required to disclose the information about the shareholdings in the Reports of Possession of Large Volume. If a company makes a cross-shareholding arrangement that may cast a significant influence on investors' judgment, investors are able to know about it in those reports. To consider about further disclosure, it is necessary to carefully examine not only the specific needs and benefits but also the costs of the additional disclosure, by taking into account the purpose of the disclosure system to provide investors with reliable information appropriately. The Financial Services Agency (FSA) will monitor the situation.
- e. The June 17, 2009, Report of the Financial System Council's Study Group on the Internationalization of Japanese Financial and Capital Markets – entitled "Toward Stronger Corporate Governance of Publicly Listed Companies" – notes that some companies already voluntarily disclose the status of their cross-holdings, and that it is appropriate to promote this kind of disclosure. The Report also notes that further consideration should be made with a view to institutionalizing the disclosure requirement so

that it would be possible to obtain information on cross-shareholdings that are occurring under explicit or implicit agreements to hold shares reciprocally or multilaterally.

- f. In May 2009, the Tokyo Stock Exchange (TSE) published for public comment a proposal to provide TSE with the power to impose remedial or punitive actions -- including making the name of the violating company public, imposing a penalty for breach of the listing agreement, and delisting -- on companies that violate any of the following four requirements with regard to the introduction of takeover defensive measures that were included in TSE's November 2007 Code of Corporate Conduct:
- (1) The listed company shall make necessary and sufficient timely disclosure concerning takeover defense measures;
  - (2) Conditions of implementation and abolishment of takeover defense measures shall not depend on arbitrary decisions by the management;
  - (3) Takeover defense measures shall not include factors which may cause extremely unstable price formation of a stock or any other factors which may cause unpredictable damage to investors; and
  - (4) Takeover defense measures shall give consideration to shareholders' rights and their exercise.

Based on the public comments received, TSE expects to finalize the proposed rules on this issue by August 2009.

## **B. Strengthening Good Corporate Governance**

1. Ensuring the Independence of Outside Directors:
  - a. The Corporate Governance Study Group (CGSG) was established in December 2008 under the Ministry of Economy, Trade and Industry (METI) in cooperation with FSA, Ministry of Justice (MOJ), and TSE in order to deliberate on the desirable rules for improving corporate governance, and it compiled and released its report this June.
  - b. The CGSG determined in its report that "independence" means having a independent position from management and sharing no mutual interests with management, and that there are two cases in which it cannot be said "independence" is present: (i) cases in which directors/*kansayaku* could be significantly controlled by management, and (ii) cases in which directors/*kansayaku* could have considerable control over management.

Moreover, taking into account the dual requirements of securing independence while ensuring the effectiveness of governance, the CGSG concluded that the framework must necessarily assume that, as a minimum, there will be an “independent” director/*kansayaku* who is not at risk of having conflicts of interest with minority shareholders and who is supposed to protect minority shareholders. In the framework, each listed company will be required to improve disclosure of its views, so that consensus regarding the most appropriate corporate governance structure for each company can be fostered through dialogue with shareholders.

- c. The CGSG also concluded in its report to require listed companies to choose either of options (1) or (2) below:
  - (1) To have an outside director as a minimum, and to disclose the role and function of the outside director etc., or
  - (2) If option a. is not chosen, to disclose facts concerning the development and implementation of the corporate governance system using the company’s own original method.
- d. TSE requires in its rules that all listed companies submit and disclose a “Corporate Governance Report” that describes the appointment of outside directors. TSE will conduct further review on the appointment of outside directors.

## 2. Taking Broad-Reaching Measures to Strengthen Corporate Governance:

- a. The Government of Japan recognizes the importance of strong and effective corporate governance mechanisms in preventing corporate misconduct and improving corporate competitiveness and earnings strength, and is committed to taking measures to strengthen corporate governance in Japan.
- b. The Financial System Council of FSA has been hosting a study group on the internationalization of Japanese financial and capital markets, following the publication of the “Better Market Initiative” released by FSA on December 21, 2007. In the study group FSA has been reviewing ways to enhance corporate governance of listed companies, and FSA has received comments which serve as useful references from foreign industries, foreign institutional investors, and other market parties. In this study group, a wide range of topics regarding corporate governance of listed companies – including issues concerning capital policies, such as third-party share issuance; structural aspects of corporate governance, such as outside directors; and monitoring of management by shareholders, such as the exercise of voting rights by institutional investors – have been discussed. The study group compiled and published a report entitled,

“Toward Stronger Corporate Governance of Publicly Listed Companies” on June 17, 2009. The specific recommendations of the study group regarding strengthening corporate governance and the protection of the rights of minority shareholders in listed companies include:

- (1) Improved accountability of management to existing shareholders, including strengthened disclosure requirements, when undertaking third-party share issuance;
  - (2) Rigorous examination by the stock exchanges where there is a risk of minority shareholders’ rights being unduly violated through squeeze outs;
  - (3) Adoption by the stock exchanges of measures that would require companies to sufficiently disclose the details of their corporate governance systems and the reasons for selecting a particular system; and
  - (4) Establishment by the stock exchanges of rules requiring disclosure of more specific details on the relationships that outside directors and auditors have with the company as well as disclosure of the company’s views on the independence of such persons.
- c. FSA will review implementation of the internal control reporting system, and consider, if necessary, the need for amendment and further clarification of the standards by taking into account the result of the review.
- d. The Advisory Group on Improvements to TSE Listing System at the TSE issued a report in April 2009 outlining its recommendations on ways to improve corporate governance of listed companies, such as to maintain a safe environment for investors. In May 2009, based on the recommendations from the Advisory Group, with a view to enhancement of corporate governance of listed companies and ensuring protection of minor shareholders, the TSE published for public comment the proposed revision of its rules regarding the following items:
- (1) On third-party placements:
    - i. To delist a company planning to undertake allocation of shares when the dilution rate is more than 300 percent, except the case when shareholders’ interests are unlikely to be violated;
    - ii. To delist a company whose controlling shareholder changed due to a third-party placement, and the soundness

- iii. To impose various measures, such as making it public, imposing a penalty for breach of the listing agreement, and delisting, if a company undertakes a share issuance which dilutes the stock value 25 percent or more or causes a change of its controlling shareholder without seeking third party opinions or shareholders' approval through procedures such as a resolution at the general shareholders' meeting; and
- (2) On reverse stock splits, to delist a company planning to undertake a reverse stock split that results in minority shareholders losing their voting rights at the general shareholders' meeting, and thus violates their shareholder rights.

Based on the public comments received, TSE expects to finalize the revision of its proposed rules regarding these matters by August 2009.

3. Ensuring Sufficient Protection of Minority Shareholders:

- a. The Companies Act explicitly provides that a director who is in a contractual relationship with the company owes good manager's duty of care to the company, which includes a duty to refrain from self-dealing that harms the interests of the company, and, consequently, that of minority shareholders.
- b. Although, it is quite difficult to stipulate that a controlling shareholder owes such duty of care to protect the interests of minority shareholders, since there is no direct contractual relationship between them, minority shareholders may bring a tort claim against a controlling shareholder when the controlling shareholder unlawfully infringes the interests of minority shareholders of the company.
- c. In October 2008, TSE issued a document called "Equity Financing and Significant Dilution" signed by its CEO to all listed companies requesting companies to deeply consider the function of the market and rights of shareholders in contemplating equity financing. Moreover, the proposed rules mentioned in B.2.d. above will strengthen the protection of minority shareholders in listed companies.

4. Encouraging Active and Appropriate Proxy Voting:

- a. In May 2009, based on the April 2009 recommendations from the

Advisory Group on Improvements to TSE Listing System, and with the objective of maintaining an environment enabling access to shareholders' meeting convocation notices at an earlier date, TSE published for public comment proposed rules that would require all listed companies to submit to TSE, at the time it provides such information to shareholders, the convocation notice and agenda of shareholders meetings, and all proxy materials, and to agree to their publication on TSE's website.

- b. The Financial System Council's Study Group on the Internationalization of Financial and Capital Markets in Japan has been considering issues regarding effecting governance through the exercise of voting rights. The study group compiled and published a report entitled, "Toward Stronger Corporate Governance of Publicly Listed Companies" on June 17, 2009. This report recommends that from the perspective of achieving accountability to shareholders, the results of individual resolutions should be disclosed, including the number of votes cast for and against, and rules should be developed by means of statutory disclosure and stock exchange rules.
- c. FSA recognizes that it is important for institutional investors, including investment managers, to exercise proxy voting properly and to monitor management adequately based on the fiduciary duty. In addition, both the Investment Trust Association and Japan Securities Investment Advisers' Association have been providing guidance to member companies to formulate guidelines on the exercise of proxy voting rights, conducting surveys on results of the proxy voting, and disclosing the survey results.

### C. **Achieving Legal System Reform**

#### 1. Promote the Provision of International Legal Services in Japan:

##### a. *Permitting Professional Corporations and Branches:*

- (1) The "foreign lawyer institution study group" established by MOJ and the Japan Federation of Bar Associations (*Nichibenren*) has been examining and will continue to investigate seriously necessary measures for the establishment of professional corporations by registered foreign lawyers (*gaiben*) and professional corporations composed of both *gaiben* and *bengoshi* in Japan, with the goal of reaching a conclusion as soon as possible within FY2009.
- (2) The Study Group will publish a draft report and seek public comments before issuing its final report. Based on the report, MOJ will consider appropriate measures.

- (3) In addition, in April 2009 a task force of the Council for the Promotion of Regulatory Reform, a government advisory body, heard the opinions of *gaiben* on whether Japanese and *gaiben* law firms should be permitted to establish branch offices without having to form a professional corporation, and asked for additional information to be submitted.
- b. *Allowing Bengoshi to Associate Freely with International Legal Partnerships:* MOJ will continue to seriously examine the legal implications and impediments, if any, of *bengoshi* becoming members of international legal partnerships. For this purpose, MOJ in 2008 diligently started a research on the practice of international legal partnerships through hearings on the views of foreign law firms operating in Japan. MOJ will continue to conduct further hearings from foreign and Japanese lawyers, as well as from other knowledgeable persons, on this issue.
- c. *Promoting Arbitration and Other Alternative Dispute Resolution:*
- (1) The Government of Japan confirms that *gaiben*, foreign lawyers, and non-lawyers are permitted to act as neutrals in arbitration procedures under the Arbitration Act regardless of the governing law or matter in dispute.
  - (2) The Government of Japan confirms that in ADR procedures other than arbitration, *gaiben*, foreign lawyers and non-lawyers whose services have been certified by the MOJ under the Act on the Promotion of Use of Alternative Dispute Resolution are able to act as neutrals in ADR procedures for services which have been certified.
  - (3) The Government of Japan confirms that *gaiben* are also able to act as neutrals in ADR procedures within the scope of their authority, as well as in ADR procedures outside the scope of their authority on a case by case basis, regardless of whether or not they have been certified by MOJ for their ADR services.
  - (4) The Government of Japan confirms that *gaiben* are permitted to represent parties in any international ADR procedures taking place in Japan at least to the extent such representation is not inconsistent with the *Gaiben* Law.
  - (5) MOJ will continue to research whether measures can appropriately be taken to provide greater legal certainty regarding the ability of *gaiben* to act as neutrals, or to represent parties, in all international ADR proceedings taking place in Japan.

d. *Ensuring a Rapid Qualification and Registration Process:*

- (1) MOJ recognizes that the qualification and registration process for *gaiben* applicants should be completed as quickly and efficiently as possible in cooperation with the applicants.
- (2) Regarding this issue, MOJ recognizes that to the extent applications can be submitted in a complete form, accompanied by sufficient descriptions of documentation or evidentiary documents, the progress of procedures resulting from such applications will be facilitated in an expeditious manner and the present situation will be improved.
- (3) MOJ drafted a revised “Manual for Application for Approval and Designation” in order to enhance the applicants’ understanding of the application process and ability to prepare their application in a manner that will facilitate its expeditious process for applicants, and asked for public comment from April to May of 2009. The manual is designed to enable applicants to precisely understand how to fill out the applications and what kind of documents should be submitted and to facilitate appropriate applications in accordance with relevant laws and regulation. In addition, in the revised manual, MOJ added some explanation about how to fill out the applications and examples of frequently used evidential documents. MOJ will carefully examine the public comments and release the revised manual during 2009.
- (4) MOJ will, as in the past, continue to grant approval and designation properly in accordance with the domestic laws. MOJ expects that the revised manual will contribute to the rapid qualification and registration process, including by having more applicants, under the guidance of MOJ, making the most of the revised manual.

2. Facilitating Criminal Prosecution of Trade Secret Theft:

- a. On February 16, 2009, METI’s Industrial Structure Council issued a report on the protection of trade secrets, including the protection of trade secrets in criminal trials. The Report recommended that METI and MOJ give further consideration to reaching a specific solution for the protection of trade secrets in criminal trials as soon as possible.
- b. In April 2009 the Diet adopted an additional resolution accompanying the enactment of amendments to the Unfair Competition Prevention Law relating to the protection of trade secrets that called on the Government of Japan to adopt an appropriate legal measure on the protection of trade

secrets in criminal trials.

- c. In light of this background, the Government of Japan is giving careful consideration to a new procedure that will ensure that the content of a trade secret will not become open to the public in a criminal trial for trade secret theft, with due regard to the Constitutional principle of public trial, and also bearing in mind the possible curbs on exercise of the rights of defendants and the necessity to secure smooth court proceedings.

## **VII. TRANSPARENCY**

### **A. Public Input into Policy Development – Advisory Groups**

1. The Government of Japan recognizes the view of the Government of the United States that the transparency of and access to advisory groups should be enhanced through the establishment of stronger transparency standards governing these groups. Advisory groups are administered by Ministries and Agencies in accordance with their respective establishment laws and regulations, the Cabinet Decision of April 1999 regarding “Basic Plan for the Rationalization of Councils, etc.,” and other guidelines and regulations. Examples of actions taken include: (a) press conferences and disclosure of related materials when certain advisory groups are established; (b) making public the date and location of such groups' meetings; (c) opening these meetings and/or meeting minutes to the public in principle as well as endeavoring to provide opportunities to hear opinions of interested parties and to have fair and balanced composition of opinions, academic background, and experiences among members of these groups when they are nominated, in accordance with the Cabinet Decision of April 1999; and (d) making publicly available lists of some of the advisory groups and their membership through "e-Gov," a government portal website (<http://www.e-gov.go.jp>).
2. The Government of Japan and the Government of the United States will continue to exchange information on best practices of transparency for advisory groups, study groups, and similar groups.

### **B. Public Comments:** The Government of Japan recognizes the need to ensure that the Public Comment Procedure (PCP) under the revised Administrative Procedure Act (APA) effectively provides meaningful opportunities for input to increase transparency and ensure fairness in the administrative rule making process.

1. The APA requires Ministries and Agencies to set comment periods of at least 30 days in principle to provide meaningful opportunities for input from the public and to fully take comments into consideration before their draft orders/regulations are made final. According to an annual survey on the implementation of the PCP in FY2007, 93.1 percent of the public comments under the APA provide comment periods of longer than 30 days. The Ministry of Internal Affairs and

Communications (MIC) will furthermore encourage Ministries and Agencies as a best practice to provide public comment periods longer than 30 days where possible; to make draft orders/regulations concrete and clear; to allow sufficient time to consider submitted comments by Ministries and Agencies where possible; and provide responses as efficiently as possible.

2. MIC has conducted and published a comprehensive annual survey on the implementation of the PCP, and appropriately sent a notice to Ministries and Agencies to operate the PCP adequately. In February 2009, MIC sent a notice about the necessity to allow sufficient time to consider submitted comments in Ministries and Agencies where possible and to publish the result at the earliest possible time. MIC will continuously encourage and promote better implementation of the procedure as necessary by maintaining close communications with relevant Ministries and Agencies. MIC will conduct and publish a comprehensive survey for FY 2008. Furthermore, MIC will improve the search tools for items subject to the PCP in the “e-Gov” web site to help people find their area of administrative concern easily in order to facilitate the submission of comments.

C. **Transparency in Regulation and Regulatory Enforcement:** The Government of Japan understands the importance of the private sector having sufficient information on regulations and ensuring that interpretations and commentaries of laws and regulations are easily available to the public through the provision of information and various standards on application of laws and will continue to consider the recommendation of the Government of the United States in this area.

D. **Promote Transparency in the Reorganization of Government Functions**

1. In February 2008, the Government of Japan established the “Council for Promoting Consumer Policy,” a consultative body attached to the Prime Minister in order to integrate consumer related policy discussed by the Council. The Council conducted extensive deliberations, including hearing views from various entities such as business organizations. Materials and summaries of discussions were promptly made available to the public after the end of each session.
2. On June 13, 2008, the Council compiled and published the final report, which includes the proposal to establish a “Consumer Affairs Agency” (CAA). Based on the report, the Government of Japan adopted “Basic Plan for Promoting Consumer Policy” as a Cabinet Decision on June 27, 2008. This Cabinet Decision became the basis of the bills to establish the CAA.
3. The bills were deliberated in the Diet, and with some amendments, were approved by a unanimous vote on May 29, 2009.
4. In formulating rules such as Cabinet Orders after the enactment of the bills, the Government of Japan intends to widely ask for opinions by following public

comment procedure stipulated in the Administrative Procedure Act and will aim to conduct a substantive public comment procedure in such a manner that will make the process as meaningful as possible.

#### E. **Foreign Translations of Japanese Laws**

1. On March 25, 2009, with due consideration to opinions of domestic and foreign experts, the Government of Japan decided to pursue a Translation Development Program for FY2010, while revising the Translation Development Program for FY2009.
2. Under the Translation Development Programs for FY2006-2010, plans are for approximately 440 laws to be translated in this period. The Government of Japan, having translated approximately 260 laws into English through April 2009, began to provide information regarding the translated laws at the newly launched Japanese Law Translation Website (<http://www.japaneselawtranslation.go.jp>). The Government of Japan will continue to ensure timely translations of laws of great interest.

### VIII. **OTHER GOVERNMENT PRACTICES**

#### A. **Government Practices Relating to Agriculture**

1. Import Regime for Maximum Residue Limits (MRLs): With regard to its enforcement of imported products for pesticide residues, the Governments of Japan and the United States have reached a conclusion in principle on a “Memorandum Between the United States Relevant Authorities and the Ministry of Health, Labour and Welfare Concerning Enforcement of Japan’s Pesticide Maximum Residue Levels,” to be formalized by signature before the end of July 2009. Both Governments will address these issues as outlined in the Memorandum.
2. Organic Crops:
  - a. *Assessment of Substances Used for Organic Crop Production*: After having examined scientific data provided by the Government of the United States on Lignin sulfonate, Potassium bicarbonate and Humic Acid, the Government of Japan announced its decision to permit only potassium bicarbonate and some uses of Lignin sulfonate for binding and anti-caking. The Government of Japan explained information necessary for a reassessment of Humic Acid. The Government of Japan received a request from the Government of the United States regarding the usage of Lignin sulfonate as floatation device on organic production, but it did not approve the usage of Lignin sulfonate as floatation device on organic production through the letter of October 10, 2008. The Government of Japan conveyed its willingness to undertake this examination if the

sufficient data to explain the necessity of the usage of Lignin sulfonate as floatation device on organic production in the United States is provided by the Government of the United States.

- b. *Setting Tolerance Level of Prohibited Pesticide Residue for Organic Crop Production*: The Government of Japan informed the Government of the United States that the Ministry of Agriculture, Forestry and Fisheries issued a press release on April 8, 2009, announcing the commencement of the process for revision of Japanese Agricultural Standard for organic plants, organic processed foods, organic livestock products and organic feeds. The Government of Japan recognized the view of an officer of the Codex Secretariat that “organic practices do not ensure that organic foods are free from residues” and that this should be one of the subjects to be discussed with stakeholders for the next revision of the Organic JAS standard in 2011.

3. Food Additives:

- a. The Government of Japan is proceeding with the authorization review for the 46 food additives and flavorings that are widely used and have been internationally confirmed as safe (for example, by the FAO/WHO Joint Expert Committee on Food Additives (JECFA)). Following an evaluation results of the Food Safety Commission (FSC), MHLW has approved the use of 26 food additives and 15 flavorings since 2003.
- b. Since this Initiative’s seventh report, thirteen additives, including nisin, have been newly designated as food additives, and these additives have been approved for use in Japan. Regarding the review of the remaining substances, MHLW will continue to work cooperatively with the FSC and the Government of the United States to expedite its review processes for all food additives and flavoring applications.

4. Cosmopolitan Pests Review:

- a. In April 2009, the Government of Japan requested additional information from the Government of the United States to complete its pest risk analyses (PRAs) based on international standards to determine the quarantine status on the cotton and bean aphids, the remaining two pests of priority interest to the Government of the United States. The Government of Japan received the requested information on May 22, 2009, for its expedited review.
- b. The Government of Japan will continue efforts to harmonize the classification of cosmopolitan pests with the international standards.

5. Pre- and Post-Harvest Enforcement System:

- a. The Government of Japan is considering revisions to its review processes for fungicides that would designate one or two expert committees as the central place for risk assessments, depending on the main purpose of an application.
  - b. The Government of the United States requested the Government of Japan to reclassify post harvest fungicides as pesticides in concert with international Codex Alimentarius standards. The Government of United States petitioned the Government of Japan to remove all labeling requirements for all post harvest fungicides applied to U.S. products. The Government of Japan will continue to consider these requests from the Government of the United States.
- B. **Wind Power Projects:** The Government of Japan understands the request made by the Government of the United States. The Government of Japan has provided and will continue to provide relevant information and, as appropriate, consider possible measures.
- C. **Special Zones:** As of April 2009, the Government of Japan has implemented 215 proposals under the Special Zones for Structural Reform program and will continue to promote the system. It will also continue to take the necessary steps to apply successful regulatory exceptions in the Special Zones on a national basis as quickly as possible (as of April 2009, 128 Special Zone measures have been applied nationwide) and consult with local governments and others concerned, including domestic and foreign companies, to expand implementation of the Special Zone system. Furthermore, if it is judged that local revitalization is significant, the regulatory exceptions should be continued (up to now, only one). Information about the Special Zone system will continue to be provided in English to the extent possible.
- D. **Consular Issues**
1. Re-entry Permits:
    - a. The Government of Japan submitted a bill to the Diet on March 6, 2009, to amend the Immigration Control and Refugee Recognition Act, for the purpose of introducing a new residence management system which will contribute to equitable control of foreign nationals.
    - b. The bill includes provisions that allow re-entry within one year without having to apply for re-entry permission for foreign nationals who have valid passports and residence cards issued under the new residence management system. The Government of Japan believes that this measure will enhance the convenience of foreign nationals who legally reside in Japan.

2. Domestic Employee Visas: The Immigration Bureau of the Ministry of Justice on March 11, 2009, issued a notification to its regional immigration bureau concerning the consistent and flexible implementation of requirements regarding entry into Japan for foreign domestic employees, as defined in the public notice. The summary of the notification is as follows:
  - a. Regarding the scope of the status of the head of an office or an equivalent position, acknowledgement of such positions shall be comprehensively decided, without being strictly bound by the name of the position and his/her title in the office, taking into account such factors as scale, form and business category of the office as well as his/her remuneration and authority in the office.
  - b. Regarding the scope of the person who has the spouse being unable to engage in the daily housework because of illness, etc., this category now includes persons whose spouses work for a company in Japan on a full-time basis in addition to those who suffer from a disease or injury. The content of notifications and assumed examples is available on the website of the Ministry of Justice (refer to <http://www.moj.go.jp/NYUKAN/nyukan83.html>).

E. **Insurance Cooperatives (*Kyosai*)**

1. The Small Amount and Short-Term Insurance Providers (SASTIP) system was introduced on April 1, 2006, to regulate previously unregulated *kyosai*. The Financial Services Agency (FSA) will review the SASTIP system within five years from the date of its enforcement (before April 2011). To conduct the review, the FSA will, as necessary, provide information on the review and meaningful opportunities for input from insurance companies, including foreign insurance companies, and other parties concerned.
2. With regard to regulated *kyosai*, the Government of Japan and the Government of the United States have discussed the view of the Government of the United States that in the near-term the Government of Japan should evaluate the consistency of regulation and supervision among *kyosai* that are regulated by various ministries other than the FSA to determine conformity to FSA standards of supervision for private insurance service providers and that such a review should be undertaken in a transparent manner with meaningful opportunities for interested parties to express and exchange views.
3. The Government of Japan and the Government of the United States have discussed the United States' view that the Government of Japan should ensure the establishment of equal conditions of competition between *kyosai* and their private sector competitors by requiring *kyosai* regulated by various ministries to: (1) pay the same taxes as their private-sector competitors; (2) contribute to a safety net system to protect depositors and policyholders from potential failures; (3) follow

the same rules and regulations as FSA-regulated insurance companies including the same reserving rules; and (4) submit to FSA supervision. The Government of Japan and the Government of the United States will continue to discuss the relevant issues in the Regulatory Reform and Competition Policy Initiative and the Insurance Consultations.

**F. Bank Sales of Insurance**

1. The Government of Japan fully liberalized the bank sales channel for insurance products on December 22, 2007. The FSA has found “no significant violations” of the measures to prevent harmful effects with regard to banks’ insurance sales practices, demonstrating that a robust bank sales channel is consistent with strong consumer protections. The ban on selling insurance products at banks had been gradually lifted since 2001 taking care to prevent harmful effects. During this process, based on the wide range of comments that were expressed through discussions with both domestic and foreign interested parties, the FSA amended the related cabinet ordinances to ensure greater protection for the consumer and these came into effect on the same day (on December 22, 2007). These related cabinet ordinances include the revision of the limit on sales of third sector insurance products by medium and small-size financial institutions, and the Government of the United States welcomes this revision. Moreover, even after the full liberalization, while continuing to monitor the insurance sales by banks and the like, the FSA will, if needed, revise measures to prevent harmful effects after approximately another three years with respect to the consumers’ protection, convenience and benefits.
2. The Government of Japan deems it important that the rules governing bank sales ensure consumer protection and are implemented fairly, including in a manner that does not favor one product, sales method or services supplier over another.
3. During the process of monitoring insurance solicitation by banks and conducting further review, development, and/or implementation of market conduct rules, the FSA will ensure meaningful opportunities for and hold hearings with insurance companies (including foreign companies), banks, and other various relevant parties based on request.

**G. Policyholder Protection Corporation (PPC)**

1. On October 14, 2008, as the global financial crisis continued to unfold, Japan’s Minister of State for Financial Services, as part of an announcement regarding a policy package to further strengthen financial system stability, stated that Japan would be extending government support for the safety net with regard to life insurance companies for three years, which is in place to protect the interest of insurance policyholders, even after the current deadline of March 31, 2009.
2. The two governments agree that it is in the best interest of Japan’s consumers and life insurance market to ensure that it has an efficient, robustly functioning safety

net system.

3. The amended Insurance Business Law which was passed in December 2008, extended the period of the existence of the financial assistance by the government-funded resources in case of an insurance company bankruptcy in the Insurance Policyholder Protection Corporation (PPC) scheme.
4. The Government of Japan and the Government of the United States discussed the United States' recommendation that the PPC is used as a last resort, including through a shift to a post-funding system to help ensure that a more efficient, sustainable safety net system is created when the current system is reviewed.
5. This amended law stipulates that the system regarding the government-funded resources to PPC will be reviewed within three years. In implementing this review, the Financial Services Agency (FSA) and the related advisory groups convened by the Government of Japan will provide private sector interested parties, including foreign insurance companies, with information on reviews as well as meaningful and timely opportunities to express and exchange views, on the deliberations of the related advisory groups to prepare for draft legislation.

#### **H. Domestication of Foreign Insurance Operations**

1. The Government of Japan and Government of the United States discussed the issue of branch conversion. The Government of Japan is aware of the following:
  - a. The Government of the United States' position is that the Government of Japan take the necessary measures so that foreign incorporated insurance companies operating branches in Japan that wish to transfer their businesses to a Japanese entity or another foreign insurance company can protect their policy holders, creditors, and maintain continuity of business through seamless process, which would include the elimination of a sales blackout rule for the transfer of portfolios between sound companies; and
  - b. The Government of Japan will continue to undertake consultations with the Government of the United States and industry, including foreign companies, to address the issue.
2. The sales blackout rule in the portfolio and business transfer provision of the Japanese Insurance Business Law aims to protect consumers who newly enter contracts subject for transfer and clarify the scope of contract subjects for transfer.
3. Also, regarding the establishment of statutory disclosure, notice and deemed approval procedure with all creditors, and allowing the transferee entity to assume all assets and liabilities of the transferring entity in transactions approved by the FSA and creditors, basically procedures for the reorganization and realignment of insurance companies should also be based upon procedures of the Japanese

Company Law.

4. There seems to be little significant legal support the permitting a "deemed license" (*minashi menkyo*), since the verification of proof, that the transferee entity is able to provide the same conditions and transaction methods as it did before the transfer, is conducted in the same manner as the verification of the new license.
5. The Government of Japan would like foreign incorporated insurance companies to consult with it individually, should they face this particular problem regarding the transfer to a Japan-incorporated entity.

I. **Independent Agents:** The Government of Japan and the Government of the United States have discussed the issue regarding the third-party distribution channels for insurance products.

## IX. PRIVATIZATION

### A. Level Playing Field for Postal Savings and Postal Insurance

1. The financial information of Japan Post Holdings Co., Ltd. (hereinafter referred to as "Japan Post Holdings"), Japan Post Service Co., Ltd. (hereinafter referred to as "Japan Post Service"), Japan Post Network Co., Ltd. (hereinafter referred to as "Japan Post Network"), Japan Post Bank Co., Ltd. (hereinafter referred to as "Japan Post Bank"), and Japan Post Insurance Co., Ltd. (hereinafter referred to as "Japan Post Insurance") are disclosed under the same regulations as other private sector companies, including those under the Companies Act, Banking Law, Insurance Business Law, other related laws and ordinances, and, when engaging in public capital market transactions, the Financial Instruments and Exchange Law. The Financial Services Agency (FSA) has sole authority over the supervision and inspection of Japan Post Bank and Japan Post Insurance under the Banking Law and Insurance Business Law, and with responsibility for applying the same standards as those applied to other banks and insurance companies, including when engaging in sales and distribution of financial services or insurance products. Accordingly, measures are implemented to ensure that the privatized postal financial institutions meet the same licensing, disclosure, and supervisory requirements as private sector financial institutions, including requisite risk management and full FSA supervision. When the Japan Post privatization process started in October 2007, the FSA established a new office with a director and 11 subordinate staff in its Supervisory Bureau. Furthermore, to strengthen the supervision of Japan Post Bank and Japan Post Insurance, the FSA engaged one additional director for the supervision of Japan Post Insurance and four staff members for the supervision of Japan Post Bank and Japan Post Insurance by August 2008. The Government of Japan will continue to ensure that the FSA properly regulates the postal financial entities under all regulations applied to other banks and insurance companies, and that the FSA and MIC properly regulate those entities under the laws on postal services privatization. The relationships and

transactions among Japan Post Bank, Japan Post Insurance, Japan Post Holdings, and Japan Post Network, are required to meet the obligations under the Banking Law and Insurance Business Law, including with respect to the arms-length rule. For purposes of accounting regulation under the Banking Law and Insurance Business Law, these four companies meet the “special relationship” criteria under the requirements of these laws.

2. The existing laws governing the privatization of Japan Post allow Japan Post Network to make agency contracts with private banks other than Japan Post Bank and to make insurance soliciting contracts with private insurance companies other than Japan Post Insurance. In terms of access to Japan Post Network’s network, it is the position of the Government of Japan that equivalent conditions of competition are secured between Japan Post Bank and other private banks and financial institutions and between Japan Post Insurance and other insurance companies respectively. The Government of Japan ensures that the Japan Post Network’s relationship with the Japan Post Bank and Japan Post Insurance are undertaken in a fair manner consistent with the arms-length rule and other rules and regulations applicable to the private sector. Japan Post Network, including its employees, is also subject to the same FSA supervision as other bank agents or insurance agents when acting as an agent or intermediary to order any financial transactions such as taking deposits, lending, exchange transactions and selling insurance products.
3. The laws on postal services privatization are designed to prevent ex-post cross-subsidization among the postal financial companies and non-financial entities in order to ensure that profits and losses are clarified and to eliminate risk of being affected by other businesses. According to the laws on postal services privatization, the Government of Japan established the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance (Public Successor Corporation), independent of the Japan Post Bank and the Japan Post Insurance, in order to separate pre-privatized accounts and contracts from accounts and contracts concluded after October 1, 2007. Pre-privatized accounts and contracts are not covered by the Deposit Insurance or Policyholder Protection scheme in case of the bankruptcy of Japan Post Bank or Japan Post Insurance. The deposit and reinsurance contracts were stipulated in the implementation plan. The implementation plan was reviewed by the Prime Minister and the Minister of Internal Affairs and Communications in the process of approval. These two ministers approved the implementation plan after hearing opinion from the Postal Services Privatization Committee (PSPC) and consulting with the Minister of Finance. In this process, the Government of Japan confirmed that profits arising from pre-privatized accounts and contracts would not be unfairly transferred to Japan Post Bank and Japan Post Insurance through the deposit and reinsurance contracts. Under the laws on postal services privatization, from October 2007, the asset management arisen from inherited pre-privatized accounts and contracts is delegated to Japan Post Bank and Japan Post Insurance by way of deposit and reinsurance contracts. As of October 2007, these deposit

and reinsurance contracts are subject to FSA inspection and supervision under the Banking Law and Insurance Business Law as well as MIC inspection and supervision under the laws on postal services privatization etc. Under the Law Concerning the General Rules of Incorporated Administrative Agencies, the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance is to prepare and disclose annual financial statements, including financial results of the reinsurance contract, audited by an independent auditor in accordance with Japanese GAAP.

4. Japan Post prepared and disclosed its financial statements as of September 30, 2007, after being audited by an independent auditor. The Valuation Committee valued assets and liabilities succeeded to the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance on fair value basis and made the meeting minutes and materials publicly available. With regard to cross-subsidization among subsidiary companies, an audit committee and an accounting auditor or a board of company auditors and an accounting auditor in each subsidiary conduct auditing in accordance with the Companies Act, Insurance Business Law, and Banking Law.
5. Since October 1, 2007, deposits received by Japan Post Bank and the life insurance products sold by Japan Post Insurance are not guaranteed by the Government. Japan Post Bank and Japan Post Insurance have explained to customers, etc. that the financial products sold by privatized postal financial institutions are not guaranteed by the Government. In addition, the Government of Japan has conducted government public relations activities to explain the nonexistence of government guarantee. Sales of such products after privatization that are misrepresented as being guaranteed by the Government are prohibited by the Banking Law and the Insurance Business Law. The FSA is monitoring whether actual sales practices by Japan Post Bank and Japan Post Insurance are in compliance with these laws. The Government of Japan is making necessary efforts so that misunderstandings about the existence of the government guarantee would not arise.
6. The Antimonopoly Act will continue to be applied to the Japan Post Group Companies (Japan Post Holdings, Japan Post Service, Japan Post Network, Japan Post Bank, and Japan Post Insurance) on the same basis and according to the same standards as applied to any private company. In this regard, the Japan Fair Trade Commission (JFTC) will continue to carefully monitor the practices of these five companies. JFTC, as appropriate, will continue to express its views on competition policy issues concerning the operation of these five companies as well as the privatization of Japan Post.
7. The Government of Japan reaffirms that the Regional-Social Contribution Fund will finance only such services that are truly necessary for the society or local regions but that are difficult for private companies to provide, and the Fund will not give advantages to Japan Post Network, Japan Post Service, Japan Post Bank,

or Japan Post Insurance. To implement the Regional Contribution Activity, Japan Post Network is obliged to make an implementation plan which is to be approved by the Minister of Internal Affairs and Communications, and to publish the plan without delay after its approval. The Government of Japan is aware of the view of the Government of the United States that public comment opportunities should be considered prior to the approval of the plan. The company is also obliged to publish a report on how the Activity was implemented within three months after the end of the plan's effective period. As mentioned above, the Government of Japan will take steps to ensure proper implementation of the Regional Contribution Activity and the transparency of the establishment and operation of the Fund.

**B. Conditions of Competition and the Introduction of Products:** Japan Post Bank and Japan Post Insurance are subject to the same laws and regulations as those applied to private financial institutions such as the Banking Law and the Insurance Business Law as well as the laws on postal services privatization. The Law of the Privatization of the Postal Services additionally imposes business restrictions on both postal financial institutions during the transitional period. The initial scope of business of Japan Post Bank and Japan Post Insurance was the same as that of Japan Post. The expansion of business scope must go through a transparent and fair procedure whereby the Prime Minister (whose power is delegated to the Commissioner of the FSA) and the Minister of Internal Affairs and Communications, upon hearing an opinion from the PSPC, decide on such expansions. Fair competitive relationships and business conditions of both postal financial institutions shall be considered when the ministers in charge make decisions on their business expansions. The introduction of new or altered insurance products by Japan Post Insurance or new non-principal-guaranteed investment products or new lending services by Japan Post Bank is reviewed through the process described above. Japan Post Bank and Japan Post Insurance must meet the same obligations and standards including risk management and compliance systems as those of private financial institutions when they sell new or altered financial products. Equivalent conditions of competition between the postal financial institutions and private financial institutions are ensured as mentioned above by the Government of Japan throughout the postal privatization process. The Government of Japan acknowledges that equivalent conditions of competition should always be ensured in expanding the business scope of postal financial institutions. The Government of Japan is aware that the Government of the United States has the view that the privatization process and implementation should conform to Japan's WTO obligations, particularly the national treatment principle of GATS.

**C. Level Playing Field for Express Carrier Services**

1. The Government of Japan reviewed its customs clearance system for international postal items and introduced, in principle, the "duty declaration" system for international postal items that are valued at over 200,000 yen from February 16, 2009. The "duty declaration" system is also applied to customs clearance procedures for international physical distribution services provided by Japan Post Service in the same manner as it is applied for other express carriers.

2. According to a March 2009 Cabinet Decision, the Government of Japan is to undertake a study on the scope (weight, price, etc.) of Express Mail Service (EMS) to which simplified customs treatment is applied compared to other carriers service, and report conclusions by March 31, 2010. The Government of Japan is aware of the importance of transparency in the study process as well as the views of the Government of the United States regarding EMS items as raised in its October 2008 recommendations.
3. The Corporate Law is applied to Japan Post Service, as it is to private companies. With regard to public disclosure, Japan Post Service is subject to the same laws and regulations as applied to other private companies. In the "Postal Services Privatization Committee's Opinion Regarding the Comprehensive Review of the Progress of Postal Privatization" dated March 13, 2009, the PSPC recommended that Japan Post Service "compil[e] data relevant to cost structures, etc., by sector."
4. In its "Fundamental Ideas" opinion dated June 18, 2008, the PSPC recommended that when Japan Post Service carries out a new international physical distribution business, it conduct this business in a manner consistent with the arms-length rule from the viewpoint of fair competition. The PSPC also recommended that the Minister of Internal Affairs and Communications confirm continually that this business is carried out in a proper manner, and report the result of the confirmation to the PSPC as a "Follow-up" of the above-mentioned opinion.

**D. Transparency**

1. The Office for the Promotion of Privatization of Postal Services, Ministry of Internal Affairs and Communications, and FSA will continue to provide timely opportunities for private sector interested parties, upon request, to exchange views with relevant officials, including on such issues as the conditions of competition between Japan Post entities and the private sector.
2. The Government of Japan recognizes the importance of transparency in the Japan Post reform process including informing the general public of any laws, regulations, guidelines, and other substantive aspects of postal services privatization through appropriate methods. The Government of Japan will also ensure transparency through the necessary use of Public Comment Procedures in accordance with the Administrative Procedures Act, and through other measures, with respect to the preparation and implementation of administrative rules, administrative official decisions, administrative guidelines, and other relevant measures. With respect to the Administrative Procedures Act, the Government of Japan will ensure that input is fully considered and, where appropriate, incorporated into draft measures before they are finalized when public comments are solicited.
3. The PSPC has made available opportunities to hear views of interested parties

regarding postal services privatization issues. The chairperson of the PSPC has announced that it would continue to do so if the Committee considers it necessary taking into account the importance of transparency in the Committee's discussion on the postal services privatization process. For example, it is prescribed by the Law of the Privatization of the Postal Services that the PSPC will implement the review about the progress of the Japan Post privatization every three years. The PSPC concluded the triennial comprehensive review on the progress of Japan Post privatization on March 13, 2009, providing opportunities for interested parties to express their views by holding hearings and accepting public comments. The Government of Japan is aware of the view of the Government of the United States that future comprehensive reviews should continue to include opportunities for all interested stakeholders to express views, including with respect to the impact of the reforms in the banking, insurance, and express delivery markets and on the equivalence of conditions of competition between the Japan Post companies and the private companies in these sectors. While recognizing the independence of the PSPC, the Government of Japan also recognizes the importance of the transparency of the PSPC.

4. Under the Standing Order of the PSPC, the PSPC has made publicly available summaries of meeting minutes as well as detailed meeting minutes in a timely manner. For each of its meetings to date, the PSPC has made the agenda items publicly available prior to the meeting, and has held the post-meeting press briefing. The Secretariat of the PSPC will continue to support the PSPC's efforts to maintain transparency in the Committee's discussions on postal services privatization. For example, the Secretariat of the PSPC will continue to make advance notice of the PSPC's agenda items publicly available (including on the relevant website) prior to each PSPC meeting.
5. Both Governments reaffirm their determination to further promote regulatory reform and, upon the request of either Government, will meet at mutually convenient times to address issues arising from the implementation of the laws on postal services privatization.

## **X. DISTRIBUTION**

A. **Airport Landing and User Fees:** The Government of Japan and the Government of the United States exchanged views regarding landing and user fees at airports in Japan.

### **B. Improving Efficiency in Customs Processing**

1. Post-Export Customs Declarations: The Government of Japan believes that its current export declaration system achieves the two goals of maintaining effective cargo processing and cargo security procedures. The Government of Japan will continue to discuss expeditious processing, while maintaining cargo security.

2. Freedom to Select Customs Office for Declaration: The Government of Japan notes the view of the Government of the United States that users of the Nippon Automated Cargo And Port Consolidated System (NACCS) should be permitted to declare express items at any convenient Customs office rather than being limited to where the cargo is physically stored. The Government of Japan believes it is important for customs brokers to establish their own offices near the place where cargo is physically stored, to identify cargo items, and to present the cargo to Customs. Meanwhile, the Government of Japan continues to study ways for Authorized Economic Operator (AEO) customs brokers to file import and export declarations.

**REGULATORY REFORM AND OTHER MEASURES BY  
THE GOVERNMENT OF THE UNITED STATES**

**I. ANTI-DUMPING MEASURES**

- A. The Government of the United States will ensure that its anti-dumping laws, regulations and other measures conform to its WTO obligations.
- B. The Deficit Reduction Act of 2005, which provides for the repeal of the Continued Dumping and Subsidy Offset Act (Byrd Amendment), came into force on February 8, 2006. For entries before October 1, 2007, duties will be disbursed as if the Byrd Amendment had not been repealed. For entries on or after October 1, 2007, duties ultimately assessed will not be disbursed to affected U.S. producers. The Governments of Japan and the United States have discussed issues regarding the disbursement of duties as mentioned above.
- C. The Government of the United States has implemented the WTO recommendations and rulings with respect to the calculation of antidumping margins in the investigation at issue in the Hot-Rolled Steel dispute. The Government of the United States will work with Congress on appropriate measures to implement the WTO recommendations and rulings concerning the U.S. legislation at issue in this dispute. In this regard, the Government of the United States notes the understanding between the governments considered at the 20 July 2005 DSB meeting concerning any decision by Japan to seek authorization to suspend concessions.
- D. The Government of the United States has explained its views regarding the Government of Japan's views on its model-match methodology with respect to the anti-dumping duty order on ball bearings and parts thereof from Japan.

**II. DISTRIBUTION AND CUSTOMS PROCEDURES**

- A. **Maritime Transport Security:** The Department of Homeland Security (DHS) and counterparts in the Government of Japan have worked through the bilateral Study Group on Secure and Efficient Trade to address issues regarding supply chain security initiatives. These exchanges have included video conferences and visits to explain to Japanese officials and industry groups how the multiple DHS security initiatives build on one another to advance a layered security strategy and risk-management approach to the global supply chain. Recognizing that information gathering and international cooperation are key to successfully securing the supply chain, DHS expects to continue productive discussions on these issues through the Study Group on Secure and Efficient Trade.
  - 1. 24-hour Rule on Advance Manifest Presentation, "10 Plus 2" Initiative:

- a. In meetings with the Government of Japan, DHS has explained its obligations to implement the 24-hour rule, including that the 24-hour rule relates only to the submission of advance cargo declarations and does not require the physical presence of the containers themselves (and that, as a measure of flexibility, last-minute changes to cargo manifest data are contemplated and permitted).
- b. U.S. Customs and Border Protection's (CBP) 10+2 interim final ruling became effective on January, 26, 2009. The regulation requires importers and ocean carriers to electronically submit additional data to CBP on vessels destined to the United States.
- c. CBP made significant changes to this rule based on the input of various industry and foreign government stakeholders, including the Government of Japan. These included allowing a number of flexibilities associated with several data elements, creating a 12-month "delayed compliance" period, and accepting additional comments from stakeholders on some aspects of the rule. Since the rule's effective date in January 2009, CBP has received more than 1.16 million Importer Security Filing (ISF) filings that have already yielded promising results. Although the formal deadline for submission of comments on the six elements of the rule subject to flexibilities expired in June 2009, CBP remains committed to coordinating closely with foreign governments as well as various industry stakeholders on the development of this initiative, going forward. The Government of the United States is aware of the Government of Japan's concerns that the 10+2 rule may lead to longer lead times, the reduction in distribution efficiency and significant increases in compliance costs, however, the Government of the United States has stressed that it remains committed to working to ensure a smooth transition in implementing the new rule in a way that facilitates trade and improves security for the benefit of all stakeholders including industry.
- d. DHS has stated that if, after consideration of all the comments submitted pursuant to the rule and the feedback received during the implementation period, it believes that business needs more time to comply with the rule, further delay of the compliance date beyond January 26, 2010, may be considered.

2. Customs-Trade Partnership Against Terrorism (C-TPAT):

- a. The C-TPAT program has a three-tiered system to provide benefits to its Importer partners. These tiers are designed to provide facilitation benefits to importer partners based on the verification of specific supply chain security measures. Tangible benefits for C-TPAT Importer partners include:

- (1) The potential for a lower targeting score (fewer inspections).
- (2) The potential for an expedited inspection (front of the line). C-TPAT importers are afforded “front of the line” inspection privileges in all modes of transportation to the extent possible and practical.
- (3) The assignment of a Supply Chain Security Specialist (a direct point of contact in CBP).
- (4) The ability to attend the annual CBP sponsored C-TPAT Supply Chain Security Seminar, and participate in the various training workshops.
- (5) The potential for expedited processing in instances of supply chain disruption (business resumption).
- (6) C-TPAT participant carriers, carrying qualifying goods for a C-TPAT participant importer, are able to use the dedicated Free and Secure Trade (FAST) commercial traffic lanes on the northern and southern borders. This provides for shorter wait times at the borders.
- (7) Being eligible for account based processing (e.g. bimonthly/monthly payments) and future CBP programs.
- (8) A C-TPAT participant company can enhance its corporate image by demonstrating that it is cooperating in the security of the country. Enhanced security has the benefit of reducing cargo theft and employee pilferage; reducing insurance costs; providing for better inventory management; and increasing profits.

- b. Security is a cost for private industry, but it is also an investment. C-TPAT provides a mechanism whereby the Government of the United States recognizes that investment, and provides benefits in accordance with the SAFE Port Act legislation. C-TPAT will continue to explore additional benefits that may be granted to participants, but all identified benefits must be administered in compliance with the Act and must be thoroughly assessed to ensure its consistency with the CBP layered enforcement strategy prior to implementation.

3. 100 Percent Scanning Requirement for U.S. Bound Cargo Containers:

- a. The Government of the United States acknowledges that the Government of Japan has serious concerns with 100 percent scanning and its potential impact on international trade and economic activities. In fulfilling Congressional

requirements for 100 percent scanning, DHS is committed to working closely with domestic and foreign trade partners and industry to move forward in a realistic and responsible manner that creates minimal disruption to port operations and the movement of commerce, and is consistent with the current risk-management and layered approach to maritime cargo security.

- b. DHS will pursue a targeted expansion strategy under which scanning systems will be deployed to a limited number of additional locations. DHS is working now to explore opportunities for future deployments. DHS intends to use scan data from these systems to enhance, not replace, the current layered, risk based approach.
- c. The United States acknowledges that the Government of Japan has concerns with 100 percent screening for U.S. inbound air cargo on passenger aircraft as well as maritime cargo. DHS intends to work closely with foreign partners and international organizations in order to address this issue.

**B. Regulations on Alcoholic Beverages:** The Government of the United States has kept, and as appropriate will continue to keep, State of California authorities apprised of Japan's recommendations under this Initiative regarding the retail sale of Japanese shochu in the State of California.

### **III. CONSULAR AFFAIRS**

#### **A. Visa Processing**

- 1. Introduction of “Electronic System for Travel Authorization” (ESTA):
  - a. The Department of Homeland Security (DHS) and the Department of State have been conducting an aggressive outreach campaign to inform prospective Visa Waiver Program (VWP) travelers of the need to obtain travel authorization via ESTA. These ongoing efforts have included publishing advertisements in print media and on travel websites, brochures, tear sheets, and fact sheets.
  - b. U.S. Government officials from Washington, D.C., and from U.S. diplomatic missions throughout Japan have conducted a variety of outreach activities intended to publicize the ESTA requirement. To date these efforts have targeted airlines, travel agencies, business groups, and the media, amongst other organizations. These efforts have included approximately 125 country-wide outreach activities in Japan during the period of June 2008 – January 2009 alone. The Government of the United States will continue to pursue outreach opportunities to inform the Japanese public of the ESTA requirement.

The Government of Japan has also proactively supported the U.S. outreach

campaign on ESTA. For example, the Government of Japan hosted several radio and TV programs featuring ESTA, and published articles and notices in magazines, websites and major Japanese newspapers.

- c. Since August 2008 more than 6.6 million applications for travel authorization via ESTA have been processed, including over one million applications from Japanese nationals, indicating the success of these outreach efforts. The overall approval rate for Japanese nationals is above 99 percent.
- d. To facilitate smooth implementation of the program, the Customs and Border Patrol (CBP) Advance Passenger Information System (APIS)/APIS Quick Query (AQQ) infrastructure will advise carriers through interactive messaging if an alien has received an ESTA, so that the carrier may appropriately approve or deny the alien boarding.
- e. DHS has been coordinating with commercial aircraft and vessel operators on the development and implementation of messaging capability that will enable carriers to receive interactive APIS messages pertaining to a traveler's ESTA status. DHS is engaged in an aggressive outreach campaign to the carrier industry to achieve compliance with APIS pre-departure and ESTA requirements, in an effort to minimize operational impact.

2. Resumption of Visa Revalidation Procedures in the United States; Efficiency in Visa Revalidation Procedures:

- a. Visa revalidation in the United States was halted in July 2004 for reasons associated with security, logistics, and U.S. law. The Government of the United States acknowledges the concerns that have been raised by the Government of Japan about the impact of this decision on visa holders. The Government of the United States has no plans to resume domestic reissuance of visas, but is offering procedures other than the resumption of domestic revalidation to address these concerns, and intends to continue discussing ongoing improvements to the visa application process that are consistent with U.S. law and policy in its discussions with the Government of Japan.
  - i. Applicants can extend their stay in the United States without renewing their visas by applying for an extension with the Department of Homeland Security. Only if the applicant departs the United States, will he or she need to reapply for a visa at a U.S. Embassy or Consulate abroad. The Government of the United States acknowledges the concern of the Government of Japan that this requirement under U.S. law may affect business travel, including by Japanese nationals.

- ii. Applicants are encouraged to apply for new visas in their home countries but may apply in a third country, provided they make a visa interview appointment. Japanese business people stationed in the United States in E-visa status can apply for reissuance of their visas at U.S. posts in Mexico subject to post resources and space availability.
    - iii. Recently, Missions in Japan instituted the State Department's new policy that allows eligible visa applicants who have submitted all ten fingerprints and are applying at the post of normal residence in Japan, to apply for a new visa in the same non-immigrant classification within 12 months of their previous visa's expiration without having to appear in person at the embassy or consulate that adjudicates their visa application. Applicants must be physically present in Japan when submitting the visa renewal paperwork.
  - b. The Government of the United States notes that the level of consular service it provides to the Japanese people is the best in the world per capita, with five U.S. non-immigrant visa processing posts in Japan. Visa procedures at the U.S. Embassy and consulates in Japan are efficient and smooth. The wait time for a nonimmigrant visa appointment in Tokyo is one to three days for tourist/business visas and the one to three days for student/exchange visitor visas. True emergency appointments are always accepted.
  - c. In order to expedite processing for E-visa applicants, the United States Government requests that Japanese businesses that hire E-visa employees in the United States keep up-to-date and accurate information with the U.S. Embassy in Japan.
  - d. The Government of the United States looks forward to continuing its dialogue on issues that affect Japanese nationals in the United States.
3. Visa Issuance and Terms of Validity:
- a. The validity of the intra-company (L) visa is limited by statute. L-1 visas may be valid for up to five or up to seven years, depending on the applicant's expected employment capacity. The validity of H-1B visas and their annual numerical limits are also controlled by the U.S. Congress. In general, the law limits an H-1B nonimmigrant to a maximum length of stay of six years. The Government of the United States acknowledges that the Government of Japan has concerns about the effect of the Congressionally-mandated quota of H visas and the fixed starting date of the validity period of H visas on employment opportunities.

- b. The Department of Homeland Security (DHS) may extend an H-1B visa holder's six-year duration of status limit in one year increments in certain circumstances.
  - c. It is possible for companies that intend to keep employees in the United States for several years to file an immigrant visa petition for the employee soon after he or she arrives in the United States on an L or H visa. In general, U.S. law does permit an alien to work in the U.S. on a nonimmigrant visa while pursuing an immigrant visa. U.S. law contemplates that family members of legal permanent residents (LPRs) who wish to accompany and reside in the United States with LPRs should apply for legal permanent residence in the United States. Alternatively, an LPR could give up his/her residency status and obtain a work visa. These limits are set in statute and Department of Homeland Security regulations.
  - d. With respect to the Government of Japan's request concerning the requirement that L-1 applicants must occasionally submit the organization chart of their companies specifying the names of employees, their titles and salaries, the Government of the United States acknowledges the Government of Japan's concerns about privacy protection and notes that consular officers request only that additional information which is necessary to determine whether the applicant meets the requirements of the visa category for which he/she is applying.
4. Extension of Employment Authorization Document (EAD):
- a. The U.S. Citizenship and Immigration Services (USCIS) will continue to strive to process the visas as expeditiously as possible within the numerical limits established by Congress.
  - b. USCIS has recently begun to issue two-year EADs to pending adjustment applicants who have submitted the proper application and who are currently unable to adjust status because an immigrant visa number is not currently available.
  - c. A very high percentage of aliens who apply for adjustment of status are permitted to continue to work without the issuance of an EAD card. For example, an L-1 or an H-1B nonimmigrant is not required to obtain an EAD card to continue his/her employment while an application for adjustment of status is pending with the Service.
  - d. USCIS is evaluating current procedures for issuing EAD cards and is aiming to achieve a six-month processing time for all cases by the end of Fiscal Year 2009.
5. Resumption of the Transit Without a Visa (TWOV) Program:

- a. On August 2, 2003, the U.S. Department of Homeland Security (DHS) and the U.S. Department of State suspended the Transit Without Visa (TWOV) and International-to-International (ITI) programs for people who would otherwise be required to obtain a visa to travel to the United States.
- b. All Visa Waiver Program (VWP) member countries' eligible citizens who obtain travel authorization through ESTA and who do not require further processing can enter and transit the United States without a visa. Japanese citizens who hold a Japanese passport may transit the United States without a visa; however, they will need an ESTA registration.
- c. Citizens of countries who are not VWP participants require a visa to transit the U.S. and must pay the machine readable visa fee, schedule a visa interview appointment, submit biometrics and obtain a valid visa to transit the United States.
- d. The Consular Affairs Bureau has a goal to keep all visa appointment wait times at 30 days or less. All U.S. embassies and consulates post their wait times online for easier scheduling. In Mission Japan there is a one to three day wait time for a visa appointment, and a facility for scheduling emergency appointments.

**B. Permission to Stay (I-94)**

1. The Government of the United States recognizes the request of the Government of Japan to extend the term of validity of the Permission to Stay (I-94). U.S. Citizenship and Immigration Services (USCIS) has prioritized backlog elimination since Fiscal Year 2006, and has made significant strides towards accomplishing its backlog elimination goals.
2. Since it was established in 2003, USCIS has, among other things, expanded electronic filing of applications and benefits to support 50 percent of the total volume; and expanded the ability for customers to access case status information via the USCIS website. USCIS will continue these efforts.
3. The Government of the United States also notes that most E-1 and E-2 visa holders often travel outside the United States and are granted an additional two year extension of stay on reentry to the United States, provided they still hold a valid visa.

**C. US-VISIT Exit**

1. The U.S. Department of Homeland Security's United States Visitor and Immigrant Status Indicator Technology (US-VISIT) will implement two air exit pilot projects to test alternatives for biometric collection from in-scope passengers

during the traveler departure process. US-VISIT will coordinate these pilots with U.S. Customs and Border Protection (CBP) and the U.S. Transportation Security Administration (TSA). There will be no private organizations involved at this time.

2. The pilot with CBP is planned to begin on May 28, 2009, at Detroit Metropolitan Wayne County Airport. CBP will collect biometric exit data at the departure gates using portable devices. US-VISIT will provide the software, hardware, technology, and training. The pilot will run for approximately 30 to 35 days.
3. The pilot with TSA will also begin on May 28, 2009, at Hartsfield-Jackson Atlanta International Airport. TSA will collect biometric exit data at the TSA checkpoint using portable devices located beyond the ticket document checker. US-VISIT will provide the software, hardware, technology, and training. The pilot will run for approximately 30 to 35 days.
4. Following completion of the pilots, an extensive evaluation will be completed. The results of the evaluation will inform the future decisions relating to biometric exit. Publication of the Final Rule is expected in early 2010. The Government of the United States will continue to discuss this issue with the Government of Japan.

#### D. **Driver's Licenses**

1. REAL ID Act:
  - a. The Government of the United States notes the Government of Japan's request to limit the "official purposes" of a REAL ID license to the minimum that are genuinely necessary. The official purposes of a REAL ID license listed by Congress in the law are strictly limited to accessing a Federal facility; boarding Federally-regulated commercial aircraft; and entering nuclear power plants. DHS will interpret the language in the REAL ID Act in accordance with the objectives of the Act.
  - b. On January 1, 2008, DHS released the REAL ID final rule concerning the implementation of the driver's licenses and identification card requirements of the REAL ID Act of 2005. The final rule was published in the Federal Register on January 29, 2008. DHS received the Government of Japan's comments on the REAL ID Act in May 2007. All 21,000 comments filed in the rulemaking proceeding were seriously taken into consideration when the final rule was drafted.
  - c. All 56 jurisdictions have been granted extensions until December 31, 2009.
  - d. The National Governor's Association (NGA) has drafted proposed Federal legislation that would provide DHS with additional flexibility in

implementing the provisions of the REAL ID Act and might possibly address some of the concerns expressed by the Government of Japan. This bill has not yet been considered by Congress.

2. Acquisition of State Driver's Licenses and Handling of International Driver's Licenses:

- a. The Government of the United States understands the Government of Japan's concerns about the impact on Japanese residents in the United States of some state requirements for obtaining driver's licenses soon after becoming residents in the United States. The Government of the United States intends to continue discussing with the Government of Japan the above mentioned problems related to international driver's licenses in order to explore a solution consistent with the Convention on Road Traffic. The Government of the United States intends to approach appropriate state authorities to communicate such concerns.
- b. The Social Security Administration (SSA) has worked successfully with the American Association of Motor Vehicle Administrators and with the Department of Transportation to eliminate requirements for a social security number (SSN) as a prerequisite to getting a drivers license in those situations where the applicants for the drivers' license are not eligible for an SSN.
- c. Some states do continue to require an SSN from drivers' license applicants who are eligible for an SSN. Although this prerequisite can be problematic for individuals, it is up to the states to determine whether they will require an SSN in these circumstances. SSA's role is to ensure that our assignment process remains efficient and that eligible applicants receive their card and number in a short time and well within the time frame of the 30-60 day requirement period for a license.

E. **Social Security Number**

1. Expedition Issuance of a Social Security Number (SSN):

- a. Before the Social Security Administration (SSA) can issue a card to eligible applicants, SSA must verify all immigration documents submitted to prove alien status with the Department of Homeland Security (DHS). Generally, SSA can verify immigration status within 10 days after the non-citizen's entry into the United States.
- b. SSA and DHS began using an enhanced version of the Systematic Alien Verification for Entitlements (SAVE) program in February 2009 which will provide faster verification of alien status in some situations. SSA and DHS continue to make enhancements to their systems and therefore

applicants can expect continued incremental improvements in the agency's alien verification processing time.

2. Issuance of Social Security Number to Dependents:

- a. SSA recognizes a non-citizen as eligible for a SSN if they have DHS work authorization or if they have a valid non-work reason for an SSN. To ensure standardized operation and application of the enumeration process, SSA Field Office personnel continue to receive refresher training and/or policy reminders on how to process SSN card applications for non-immigrants.
- b. In some situations proof of marital relationship to certain individuals authorized to work is acceptable in lieu of proof of the individual's authorization to work (Employment Authorization Document – EAD). Since in Japan the Family Registry is the official form used to establish evidence of marriage, SSA accepts the Japanese Family Registry as evidence of marital relationship. SSA generally accepts translations of the Japanese Family Registry issued by the Japanese Embassy/Consulate.
- c. Whether SSA assigns SSNs to dependent children of temporary foreign workers is based on whether such dependents have work authorization from the Department of Homeland Security (DHS). E-1, E-2, and L-2 dependent children are not allowed to work in the United States under DHS regulations. They may qualify for a non-work number under only very limited circumstances.

#### IV. PATENT SYSTEM

The Government of the United States and the Government of Japan reaffirm mutual support for effective and substantive patent law harmonization efforts. The Government of the United States is pleased to continue discussions with the Government of Japan and will take into account Japan's recommendations in this area. As appropriate, the Administration will continue to work with the U.S. Congress on patent issues.

- A. **First-to-Invent System:** The Government of the United States acknowledges that its first-to-invent system is unique. While the first-to-file system is used in most countries, it remains a point of discussion in the United States. Legislation is currently pending in both the U.S. House of Representatives and the U.S. Senate (H.R.1260, S.515, and S.610), which contemplates a change in the U.S. law from first-to-invent to first-to-file. The Senate Judiciary Committee endorsed S. 515 for consideration by the full Senate, and the House held hearings but has not taken further action on H.R. 1260. The Government of the United States will continue to provide updates on the status of legislation as appropriate to the Government of Japan. In addition to these legislative efforts, the U.S. Patent and Trademark Office (USPTO) remains open to continuing discussions on harmonization with Japan and other World Intellectual Property

Organization (WIPO) Group B member countries concerning a possible substantive patent law agreement, the relevant draft provisions of which are written from a first-to-file perspective.

- B. **Early Publication System:** Currently pending legislation in both the House and Senate (as mentioned immediately above) do not address this issue. However, in 1999, the United States passed Public Law 106-113 which provided for the publication of patent applications. While this law does permit a patent applicant to request non-publication under certain circumstances, nearly 93 percent of all applications are published. Since this law was passed, the United States Congress has considered removing this exception to publication, but those legislative attempts have not been successful. The Government of the United States acknowledges and will continue to discuss the Government of Japan's concerns about this exception.
- C. **Reexamination System:** The Government of the United States recognizes that *ex parte* and *inter partes* reexamination limit interaction and only apply to specific grounds of patentability. New provisions in the proposed legislation (H.R. 1260, S. 515, and S. 610) contemplate post-grant opposition proceedings that would expand the scope of post-grant review as well as proposing changes to the reexamination system.
- D. **Restriction Requirement Due to Non-Fulfillment of Unity of Invention:** The Government of the United States recognizes that its restriction practice, as applied to non-Patent Cooperation Treaty (PCT) applications, differs from unity of invention practice under the PCT. The Government of the United States continues to study these differences in practice, but notes that applicants filing with the USPTO have a choice to file either a national application or through the PCT in order to receive treatment according to either U.S. restriction practice or PCT unity of invention practice.
- E. **Hilmer Doctrine and Article 102(e) of the Patent Act:** The Government of the United States recognizes that the Government of Japan has concerns regarding the Hilmer Doctrine and Article 102(e) of the Patent Act. It should be noted that the legislation introduced in the House and Senate addresses this issue favorably from the perspective of the Government of Japan. Furthermore, the USPTO remains open to discussing this issue in patent law harmonization talks with Japan and other WIPO Group B member countries.
- F. **Information Disclosure Requirement of Prior Art:** The Government of the United States acknowledges and continues to consider the Government of Japan's concerns over USPTO Information Disclosure Statement (IDS) requirements. The Government of the United States notes the views of the Government of Japan and will continue to consider these views in relation to the balance between imposing obligations on patent applicants on the one hand, and promoting a higher quality, more effective and efficient examination process on the other.
- G. **Plant Patent:** The Government of the United States acknowledges the concerns expressed by the Government of Japan regarding the manner in which the grace period

provisions provided under the International Convention for the Protection of New Varieties of Plants (UPOV) interact with the grace period provided under U.S. law with respect to plant patents. There have been several bills introduced in the House and Senate in the past several years that would address these concerns, but none have been enacted. At the present time, USPTO is not aware of any pending legislation that addresses this issue. The Government of the United States will continue to consider the issue in view of the concerns expressed by the Government of Japan.

## **V. GOVERNMENT PROCUREMENT**

The Government of the United States waives the application of discriminatory provisions, which include the Buy American Act of 1933 (BAA), for procurements subject to the WTO Agreement on Government Procurement (GPA). The Government of the United States only applies “Buy American” preferences to procurement that is not covered by the GPA.

### **A. Safe, Accountable, Flexible, Efficient Transportation Equity Act – A Legacy for Users**

1. SAFETEA-LU authorized Federal surface transportation programs for highways and transit for 2005-2009 and continued the application of certain restrictions on highway and transit grants. Where such projects are above the GPA thresholds, suppliers from GPA Parties may bid on them. However, Note 5 in the U.S. Annex 2 to Appendix I of the GPA states that: "The Agreement shall not apply to restrictions attached to Federal funds for mass transit and highway projects." Therefore, the Government of the United States does not waive these “Buy America” restrictions attached to the Federal funds for those projects and thus the restrictions continue to apply. The United States will continue to comply with its GPA obligations in conducting procurements covered by the GPA. The Government of the United States takes note of the Government of Japan’s concerns regarding “Buy America” and the Government of Japan’s ongoing interest in access to U.S. mass transit projects.
2. Decisions issued by the U.S. Department of Transportation/Federal Transit Administration (FTA) in response to requests for waivers to the “Buy America” restriction, including requests for waivers based on the public interest, may be found at: [http://www.fta.dot.gov/laws/leg\\_reg\\_598.html](http://www.fta.dot.gov/laws/leg_reg_598.html). These waiver decisions were issued from August 20, 1999, to the present under SAFETEA-LU and previous authorizing legislation. They include waiver decisions based on non-availability, cost-differential (25 percent) and the public interest. FTA has in the past granted public interest waivers in order to, for example, accelerate delivery schedules, facilitate safety and performance testing, and acknowledge technological advances and innovation overseas. Any interested party, including a foreign company, can petition FTA for a public interest waiver. Any interested party may petition FTA for a non-availability waiver, as well, but only grantees can petition FTA for a cost-differential waiver. FTA publishes proposed public

interest waivers in the *Federal Register* and allows a maximum period of seven days for public comments. Any interested parties can file their comments electronically at: <http://www.regulations.gov>. The waiver decisions posted on the FTA website illustrate the treatment of prior waiver requests. However, each waiver request is considered on its own merits and therefore it is not possible to predict with any certainty whether a future request will be granted.

3. Where a Federal surface transportation project for highways or transit is undertaken using grants under the American Recovery and Reinvestment Act of 2009 (ARRA), Title XII of the ARRA provides that the “Buy America” provisions of SAFETEA-LU will apply, rather than the “Buy American” provisions of the ARRA.

## B. **Regulations Concerning Construction of U.S. Military Bases**

1. Requirement to Use U.S.-Flag Vessels for the Transportation of all Supplies and Materials Identified to DoD Contracts:
  - a. Regarding the laws and regulations which require the use of U.S.-Flag vessels for transportation of all supplies and materials identified to U.S. Department of Defense (DoD) contracts (DFARS247.572), The Cargo Preference Act of 1904 is applied to the transportation of such supplies and materials in all U.S. DoD contracts.
  - b. The Government of the United States understands the concerns raised by the Government of Japan. The Government of the United States confirms that the requirement to use U.S.-flag vessels is the same for all offerors and requirements will be applied in such a way that all prime contractors with the government have an equal chance. This includes U.S., Japanese, and WTO/GPA entities. As a result, U.S., Japanese, and WTO/GPA contractors will have the same access to U.S. flag shippers.
2. Requirement of Performance Bond and Payment Bond:
  - a. Federal Acquisition Regulation requires contractors performing construction work ordered by the Federal Government to furnish bond for 100 percent of the contract price as performance guarantee and payment guarantee (FAR 28.1). This requirement is non-discriminatory as all contractors, including foreign contractors, are subject to the requirement. In this regard, bonds issued by corporations incorporated under the laws of a State, the District of Columbia, or territory or possession of the United States, such as U.S. corporate subsidiaries of Japanese insurance companies, are valid if approved by the authorities concerned under U.S. Treasury standards for bonding issuance (31 CFR 223.5). Cash, irrevocable letters of credit, or U.S Treasury securities are qualified as a substitute for performance and payment bonds.

- b. The Department of Defense has considered Japan's request regarding the lowering of performance and payment bond requirements from 100 percent to a lower percentage. The U.S. Government has explained that there is no indication that the requirement would have an adverse competitive effect on firms and confirms that the requirement to have 100 percent performance and payment bonding is the same for all offerors.

C. **Price Changes for Contract Agreements for Public Works Projects:** The Government of the United States notes that price escalation clauses may be used on contract agreements for public works projects as explained in FAR 36.207(c), and that the Federal Government may enter into fixed price construction contracts with economic price adjustment clauses in accordance with FAR 16.203-1 through FAR 16.203-4. The Government of the United States explained in detail the process and justification for the use of the price escalation clauses to the Government of Japan and that contracting officers consider market conditions and often solicit and consider opinions from the private sector through meetings during the procurement process.

## **VI. EXPORT-RELATED REGULATION**

### **A. Re-export Controls**

- 1. U.S. re-export controls apply to all countries, and the U.S. laws governing the development and implementation of these controls do not allow for the exemption of any specific country. However, in response to the concerns raised by the Government of Japan, the Bureau of Industry and Security (BIS) continues to look for ways to assist in this area, and has:
  - a. Posted re-export control guidance on the BIS website;
  - b. Developed a re-export control webinar that is accessible via the new BIS Online Training Room;
  - c. Hosted seminars in Japan, with a specific focus on U.S. re-export controls; and
  - d. Positioned export counselors on both the east and west coasts of the United States who are available via telephone and email to answer questions about U.S. export and re-export controls.
- 2. There is no U.S. law requiring U.S. companies to provide classification information, or Export Control Classification Numbers (ECCNs), to their customers. Moreover, BIS has received the legal opinion that the Bureau's principal statutory authority requires that individual company's classification information be treated as confidential and such information may not be published or disclosed by BIS. Accordingly, BIS is prohibited from making company

classification information public. However, BIS has developed another way for U.S. exporters to share classification information, within the confines of U.S. law:

- a. BIS created a Commodity Classification Webpage and published a solicitation for companies having commodity classification information available on their company websites, and/or export control points of contact, to provide the relevant information to BIS for inclusion on the webpage.
  - b. This approach has a broader impact than publishing ECCNs, as it is not restricted to products for which BIS has issued formal commodity classifications, and it allows for the inclusion of information other than that which may appear on a formal commodity classification, such as a company's export control point of contact.
  - c. BIS will encourage U.S. exporters to participate in this method of providing commodity classification information.
  - d. BIS always encourages U.S. exporters to supply ECCNs to re-exporters as a good customer service. Consequently, if a re-exporter is unable to locate a U.S. exporter's information on the webpage, BIS encourages re-exporters to contact U.S. exporters directly to request the classification information they desire.
3. The U.S. Government will continue to evaluate and discuss the issues raised by the Government of Japan.

## **VII. STANDARDS AND CRITERIA**

### **A. Promotion of the Metric System**

1. The U.S. National Institute of Standards and Technology (NIST) reaffirms the significance of metric system use in the United States and it actively promotes the voluntary adoption and benefits of the metric system in trade and commerce within the United States with the intention of continuing efforts. NIST works with the U.S. Metric Association (a private sector organization) and other partners to provide public information through websites and other tools, outreach efforts, and responds inquiries annually to educate industry and the public.
2. Metric units are permitted in 96 percent of U.S. states on packages subject to their jurisdiction, including products such as automotive accessories, clothing and wearing apparel, and household furnishings. Two U.S. states currently have legal prohibitions against metric labeling. One of the states, New York, is engaged in the regulatory process to allow metric labeling. NIST, along with other organizations, continue to work with the remaining state, Alabama, to remove legal prohibitions against metric labeling.

3. Amending the federal Fair Packaging and Labeling Act (FPLA) is a priority of the NIST Metric Program. NIST continues to work towards building U.S. industry support for Congressional action to modify the law to permit metric labeling.
4. Expanding use of the metric system is anticipated as new technologies enter the U.S. marketplace. For example, the U.S. National Work Group for the Development of Commercial Hydrogen Measurement Standards - Fuel Specification Sub-committee has proposed Hydrogen Fuel method of sale based metric units (kilogram and pascal) in commercial sales and on street signs. If implemented, the U.S. approach would be consistent with the global hydrogen marketplace.
5. U.S. healthcare institutions are increasingly switching to exclusive SI measurements for patient care to lower the potential for patient safety errors and increase patient care quality. The Joint Commission issued an alert in 2008 to member organizations to weigh pediatric patients in kilograms to reduce medical errors.
6. NIST will continue to exchange views and information with the Government of Japan and, as appropriate and where possible, work with the Government of Japan on individual issues.

**B. Equivalence Determination on Organic Crop Products:** On April 15, 2009, the Government of the United States presented a letter to the Government of Japan officially completing the recognition of Japan's conformity assessment procedures for organic certification. The Government of the United States expressed its views on the possibility for determining equivalence between the Organic JAS system and the U.S. National Organic Program, once the Government of Japan officially eliminates its zero tolerance for chemical residues in organic products.

**C. Mitigation of Export Quarantine Requirements for Japanese Produced Unshu Oranges:** Regarding the Government of Japan's request that import conditions be reduced, the Government of the United States shares the understanding with the Government of Japan that reducing these conditions should be based on a review of the current pest risk assessment for Japanese unshu oranges. The Government of the United States is currently reviewing the information and technical materials received to reevaluate the pest risk analysis and will share the result with the Government of Japan as soon as possible.

## **VIII. STATE-BASED REGULATIONS**

### **A. Environmental Regulations**

1. The U.S. Environmental Protection Agency (EPA) notes the concerns of the Government of Japan regarding harmonization of environmental regulations on

recycling of electronic products, and has been taking the following measures in cooperation with other organizations with the intention of making further efforts.

2. EPA is aware of the challenges caused by the growing patchwork of state e-waste laws in the United States, many of which have similar elements. The National Electronics Recycling Infrastructure Clearinghouse (NERIC) has been established through an initiative of the National Center for Electronics Recycling (NCER), a non-governmental organization that represents a group of states on the issue of electronics recycling. The NERIC has not been formalized, but EPA provided initial funding with the expectation that it might be formalized in the future. If created, the NERIC will be an initiative of the states (i.e. not sanctioned by the Federal Government) and participation will be on a voluntary basis.
3. Regarding the harmonization of environmental regulations, the Government of the United States explained that responsible officials of state governments have meetings every two months to cooperate with each other for the harmonization.
4. Common themes in all of the state laws have begun to emerge and NCER is helping to standardize these requirements; for example, a central location for electronic manufacturers to register their company with states that have enacted e-waste legislation is now being developed through the NERIC.
5. With respect to the Government of Japan's request for a compilation of information on individual industrial product standards and related regulations, the NERIC website <<http://www.ecyclingresource.org/ContentPage.aspx?PageID=1>> contains much of this information and efforts will continue to combine this information for easier reference. For example, the Compliance Calendar link <<http://www.ecyclingresource.org/ComplianceCalendar/index.aspx>> provides an easy to read table format for manufacturers' deadlines for certain requirements in each state.

## **IX. EXTRATERRITORIAL APPLICATION**

- A. **Iran Sanctions Act:** The Government of the United States remains concerned about Iran's continued failure to verifiably suspend uranium enrichment and comply with its international obligations. The Government of the United States reiterates that the Iran Sanctions Act (ISA, previously known as the Iran and Libya Sanctions Act, or ILSA) reflects the ongoing U.S. policy of opposing investment in Iran's petroleum sector and that the provisions of the Act apply to those who engage in activities covered by the statute, without distinction by nationality. The Government of the United States shares the concerns of the Government of Japan regarding consideration of new legislation such as the Iran Counter-Proliferation Act. Such measures would limit the President's flexibility in implementing a comprehensive foreign policy, and the administration has clarified its position to the U.S. Congress. The legislative history of the Act indicates a concern by Congress that the law be applied in a manner consistent with the international

obligations of the United States. The Government of the United States welcomes its continued dialogue with the Government of Japan.

**B. Cuban Liberty and Solidarity Act of 1996**

1. The Government of the United States understands the concerns of the Government of Japan regarding the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 (Public Law 104-114). As noted by the Government of Japan, since the enactment of the Act the President has, every six months, suspended the right to bring an action under Title III (which provides for civil suits against persons who traffic in expropriated property), based on findings that such suspension is necessary to the national interests of the United States and will expedite a transition to democracy in Cuba. The duration of the suspension is fixed by statute and cannot exceed six months at a time (P.L. 104-114, Sec. 306).
2. Most recently, on January 16, 2009, the President sent a letter to Congress consistent with the Act to suspend for six months beyond February 1, 2009, the right to bring an action under Title III of the Act.

**X. COMPETITION POLICY**

- A. The federal antitrust agencies of the United States continue to look for opportunities to express their views on the appropriate scope of exemptions and immunities from the application of the federal antitrust laws with a view to promoting competition for the benefit of U.S. consumers.
- B. In addition, the U.S. antitrust agencies continue to advise state entities on the potential competitive impact of pending governmental actions, including as concerns proposed exemptions and exceptions. For example:
  1. On March 18, 2009, staff of the Federal Trade Commission (FTC) submitted written comments to the Minnesota legislature opposing legislation that would exempt certain activities by Minnesota health care cooperatives from state and federal antitrust laws, including price fixing and collective negotiation of terms of dealing with purchasers of health care services. The FTC staff commented that none of the provisions in the legislation are likely to prevent the harmful effects that arise from immunizing price fixing. Furthermore, the proposed legislation -- by depriving health care consumers of the protections of the antitrust laws and the benefits of competition -- would result in patients, employers, insurers, and federal, state and local health care programs all paying more for medical care. The FTC staff also noted that an antitrust exemption is unnecessary to improve health care quality.
  2. On September 15, 2008, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) submitted a joint statement to the Illinois Task Force on Health Planning Reform regarding an Illinois law requiring a Certificate of Need

(“CON”) before a new hospital can be approved. The U.S. antitrust agencies pointed out the benefits of competition in the health care market and the significant anticompetitive risks posed by CON laws, and recommended that the Task Force seriously consider whether the Illinois CON law should be repealed.

3. On April 17, 2009, the DOJ submitted comments to the Montana Supreme Court on a proposed rule defining the unauthorized practice of law in a manner that could increase prices to Montana consumers by unduly barring non-lawyers from competing with lawyers for a range of services. The DOJ recommended that the Montana Supreme Court avoid unnecessary restrictions on such competition by limiting the definition of the unauthorized practice of law to situations where specialized legal skills are required and an attorney-client relationship is present.

## **XI. LEGAL SYSTEM/LEGAL SERVICES**

- A. The Virginia Supreme Court adopted a foreign legal consultant rule that came into effect on January 1, 2009. There are now 30 U.S. jurisdictions that have adopted foreign legal consultant systems, with those jurisdictions accounting for more than 88 percent of the total legal services business in the United States.
- B. The Government of the United States acknowledges the Government of Japan’s concern that 21 states in the United States still do not have a foreign legal consultant system, and continues to take positive action to encourage the American Bar Association (ABA) to engage in an active dialogue with the state bar associations and state supreme courts with the goal of encouraging all states to adopt foreign legal consultant systems based on the ABA's Model Rule for the Licensing and Practice of Foreign Legal Consultants.

## **XII. MARITIME TRANSPORT BUSINESS**

- A. **Merchant Marine Act of 1920 and Reporting Requirements Regarding Japanese Ports**
  1. The Government of the United States and the Government of Japan exchanged views regarding the Merchant Marine Act of 1920. The Government of the United States took note of the Government of Japan’s concerns on this matter, and indicated its own continuing concerns about conditions at Japanese ports.
  2. The Government of the United States again communicated its interest in receiving information from a variety of sources on conditions at Japanese ports. Such information could enable the Federal Maritime Commission (FMC) to consider terminating its proceeding or modifying the reporting requirements it has placed on U.S. and Japanese flag carriers. For example, the Government of the United States understands that the Government of Japan considered providing, on a government-to-government basis, a translation of Japanese law changed in 2006 that may be relevant to the FMC’s ongoing review of conditions at Japanese ports. The Government of the United States hopes that translation of the 2006 law

would be provided to the Commission, as this could serve as a substitute for the current requirement upon Japanese carriers to furnish a translated text for the Commission's review. Such a government-to-government accommodation could result in the reduction or elimination of the reporting requirements on Japanese carriers.

- B. **Ocean Shipping Reform Act of 1998 (amendment to Section 19 of the Merchant Marine Act, 1920):** The Government of the United States explained to the Government of Japan that the 1998 amendment to section 19 of the Merchant Marine Act, 1920 clarified authority already granted to the Federal Maritime Commission. The Government of the United States noted the Government of Japan's continuing concerns on this issue.
- C. **Maritime Security Program:** The Government of the United States exchanged views with the Government of Japan on this national security program. The Government of the United States reaffirmed its commitment to the keeping the Government of Japan informed of the list of the dedicated vessels and of any other changes of material impact to this program. The Maritime Security Program is transparent and all information is publicly available at the Maritime Administration's website: (<http://www.marad.dot.gov/programs/index.html>).
- D. **Cargo Preference Measures:** The Government of the United States and the Government of Japan exchanged views on Cargo Preference Measures including the law requiring that the transport of Alaskan North Slope crude oil be done on U.S.-flag ships. The Government of the United States took note of the opinion of the Government of Japan that such measures may distort conditions for free and fair competition in the international maritime market. The Government of the United States explained that the measures affect less than one percent of the United States' total ocean borne foreign trades and have a beneficial impact on the U.S. merchant marine industry by providing an incentive for vessels to remain in the U.S. fleet. With regard to the law requiring the transport of Alaskan North Slope crude oil be on U.S.-flag ships, the Government of the United States explained that the last Alaskan crude oil to be exported was in April 2000. Since that time all Alaskan crude oil production has moved to the U.S. West Coast market for refining and domestic consumption.
- E. **California: Container Fee Program / Clean Truck Program**
1. Container Fee Program: The bill to impose a fee of 30 dollars per TEU, SB 974, was vetoed by the Governor of California in 2008. There are no indications at this time that the bill will be reintroduced.
  2. Clean Truck Program: The Government of the United States shares the Government of Japan's concerns about the Clean Truck Program of the Port of Los Angeles and the Port of Long Beach. The U.S. District Court for the Central District of California issued an injunction against the Ports April 28, 2009, pursuant to a court complaint filed by the American Trucking Associations.

Among other things, the injunction prohibits the Ports from requiring that licensed motor carriers use employee-drivers to dray containers. In other words, this element of the injunction allows the drayage truck industry at the Ports to continue using independent owner operators of drayage trucks. The Federal Maritime Commission commenced a separate action under the Shipping Act of 1984 in the U.S. District Court for the District of Columbia to enjoin the employee-driver mandate. The Commission's District Court proceeding is still in progress.

### **XIII. COMMODITY MARKETS**

- A. **Enhancing Transparency of Commodity Futures Markets:** On October 31, 2008, the U.S. Commodity Futures Trading Commission (CFTC) concluded an arrangement to enhance cooperation and collaboration with Japan's Ministry of Economy, Trade and Industry (METI) and the Ministry of Agriculture, Forestry and Fisheries (MAFF). The arrangement provides a framework for an enhanced dialogue on issues of mutual interest, including identifying regulatory policies/developments of mutual concern in the commodity derivatives markets, building on existing arrangements to improve coordination on the exchange of information regarding cross-border commodity derivatives trading, and consulting regularly on regulatory policies and market issues.

### **XIV. FINANCIAL SERVICES**

#### **A. Insurance Business**

1. Unification of State-Based Insurance Regulations:
  - a. The Government of the United States is aware of the Government of Japan's view that the current approach to state-based insurance regulation for Japanese insurance firms in the United States continues to be a source of concern for the Government of Japan, and acknowledges the Government of Japan's continued interest in the U.S. Government's initiatives relating to reform of the federal regulatory system.
  - b. On June 17, 2009, the Department of Treasury released a plan to modernize financial regulation and supervision. The financial regulatory reforms proposed aim to create a more stable regulatory regime that is flexible, effective, and able to secure the benefits of financial innovation while safeguarding the financial system. The plan calls for the establishment of the Office of National Insurance within Treasury. The Government of the United States notes that the Government of Japan hopes that the United States will adopt new regulatory measures proposed in the plan to address the concerns of Japanese insurers operating in multiple states and enhance prudential supervision of insurance groups.

- c. The National Association of Insurance Commissioners (NAIC) recognizes the benefits of harmonization of licensing and regulatory process. Efforts by the NAIC to harmonize state practices and streamline regulatory standards and processes for insurance products continue to advance. The Interstate Insurance Compact (Compact) is a key state-based regulatory modernization initiative that enhances the efficiency and effectiveness of the way asset-based insurance products (such as life insurance) are filed, reviewed, and approved in the United States. The Compact's new streamlined processes provide speed-to-market for the insurance industry by promoting uniformity through application of national product standards embedded with strong consumer protections. The Compact became operational in June 2007 and as of May 2009, 35 state legislatures and Puerto Rico have adopted the Compact. However, the Government of the United States recognizes that the Compact is limited to life insurance and does not cover all states and all area of insurer's business.
  2. Reinsurance Collateral Requirement: The Government of the United States notes the continued concerns raised by the Government of Japan regarding reinsurance collateral requirements. The NAIC continues to make progress towards introduction of its Reinsurance Regulatory Modernization Framework. If implemented, the Reinsurance Regulatory Modernization Framework proposes to eliminate collateral requirements for the top rated non-U.S. reinsurers and reduce it by 90 percent for Tier 2 non-U.S. reinsurers and 80 percent for Tier 3 non-US reinsurers. The need to retain 10 percent and 20 percent collateral for Tier 2 and 3 companies, respectively, is a prudential matter. However, as part of the proposed Framework, the NAIC will consider reviewing the collateral requirements for Tier 2 and Tier 3 non-U.S. reinsurers after two years of its implementation, to determine whether they are appropriate, including considerations of market access developments for U.S. insurers in non-U.S. jurisdictions. The Government of the United States will continue to ensure that its reinsurance collateral requirements and potential amendments are consistent with its WTO commitments.
  3. Trusteed Surplus Requirement: The Government of the United States notes the concerns of the Government of Japan regarding trusteed surplus requirements. The NAIC continues to meet with the General Insurance Association of Japan to discuss and further research this issue. The Government of the United States will facilitate communications, as appropriate, between the NAIC and the Government of Japan on trusteed surplus requirements.
- B. **Samurai Bonds**: The Government of the United States has reviewed its foreign targeted registered obligation (FTR) rules in light of technological and financial market developments. Those rules provided that there would be no obligation to deduct and withhold tax on interest paid on registered bonds targeted to foreign markets, if certain conditions were met. The FTR rules were thus inconsistent with the development of the documentation and reporting required under the "qualified intermediary" (QI) regime,

because they permit issuance of a registered form bond without information or tax reporting to the IRS. Consequently, the United States government removed the FTR rules for bonds issued after 2006, with a transition period for certain bonds issued during 2007 and 2008 with a stated maturity of not more than 10 years from the date of issuance. The transition period has not been extended.

## **XV. TELECOMMUNICATIONS**

**A. Entry Requirement in the Submission Form for the Importation of Radio Frequency Devices into the United States:** The Federal Communications Commission (FCC) is in the process of reviewing Form 740, a form that must accompany certain radio frequency devices imported into the United States. The FCC has received comments from various interested parties, including from Japan, and plans to make changes to this form, taking such comments into account.

### **B. Procedures for Export Licenses, Approval of Technical Assistance Agreement and Other Measures Concerning Commercial Satellites**

1. On January 22, 2008, an Export Control Directive was issued that instituted a set of reforms designed to expedite and improve the way that the Government of the United States licenses the export of defense equipment, services and technical data. The reforms included committing additional funding and resources to the adjudication of export control licenses, and new guidelines that require a decision by the Government of the United States on defense trade export license applications within 60 days, absent a strong reason for additional time.
2. The Directive has resulted in significant improvements in the manner in which the Department of State adjudicates export license and technical assistance agreement (TAA) applications. Since February 2008, average processing times for export license applications have held steady at an average of 16 days, an improvement of about 50 percent over average processing times during the prior year. Work continues on other technological and procedural upgrades to the licensing process.
3. All changes to export control regulations are posted in the Federal Register; the most significant of these changes are opened to public comment.
4. The Department of State hosts a website, [www.pmdtc.state.gov](http://www.pmdtc.state.gov), where interested parties can find up-to-date information on average processing times, recent regulatory changes, and a variety of other issues associated with our operations.

### **C. Competition in the Navigation Devices Market for Cable TV Services**

1. The Government of the United States will continue a dialogue with the Government of Japan on how the FCC enforces Section 629 of the Telecommunications Act with a view to ensuring choice in the market for navigation devices (set-top boxes). The Commission implemented this directive

starting in 1998 through the adoption of the “integration ban,” which established a date after which cable operators no longer may place into service new navigation devices (*e.g.*, set-top boxes) that perform both conditional access and other functions in a single integrated device; and a “Plug and Play Order,” established requirements for unidirectional digital cable product in 2003.

2. In June 2007, the FCC initiated a rulemaking to establish reasonable technical requirements to facilitate a competitive market for the supply of interactive navigation devices. As of May 2009, based on results of negotiations between the cable and consumer electronics industry, 18 major IT and consumer electronics companies have reached agreement on technical requirements for bidirectional compatibility in navigation devices.
3. Given these developments, the FCC has not intervened to impose technical requirements, but consistent with Section 629, it will continue to monitor developments in the market to ensure that a competitive market for navigation devices develops.

**D. Policies Concerning Establishment of Advanced Information Communication Infrastructure**

1. On February 17, 2009, the U.S. Congress passed the American Recovery and Reinvestment Act, which included over \$7 billion for the promotion of broadband services, including establishment of National Telecommunications and Information Agency’s (NTIA) \$4.7 billion Broadband Technology Opportunity program (BTOP). The purposes of the BTOP include accelerating broadband deployment in unserved and underserved areas and ensuring that strategic institutions that are likely to create jobs or provide significant public benefits have broadband connections. NTIA anticipates that the first wave of awards under its program will be made by fall 2009.
2. The Conference Report on the Recovery Act states *inter alia* that NTIA should consult with the FCC on defining the terms “unserved area,” “underserved area,” and “broadband.” The Recovery Act also requires that NTIA shall, in coordination with the FCC, publish non-discrimination and network interconnection obligations that shall be contractual conditions of grant awards, including, at a minimum, adherence to the principles contained in the FCC’s broadband policy statement (FCC 05-15, adopted August 5, 2005).
3. On March 12, 2009, NTIA issued a Notice of Inquiry (NOI), soliciting comments on various aspects of the BTOP program. Over 1,600 written comments have been received to date. These comments will be taken into consideration in drafting a Notice of Funds Availability (rules describing how to apply for funds), which is expected to be issued during the summer of 2009.

4. On April 8, 2009, the FCC adopted a Notice of Inquiry that began a proceeding to create that national broadband plan, to provide a roadmap toward achieving the goal of ensuring that all Americans reap the benefits of broadband. The FCC must deliver the plan to Congress by Feb. 17, 2010. The Recovery Act requires the plan to explore several key elements of broadband deployment and use, and the FCC now seeks comment on these elements, including:
  - a. The most effective and efficient ways to ensure broadband access for all Americans.
  - b. Strategies for achieving affordability and maximum utilization of broadband infrastructure and services.
  - c. Evaluation of the status of broadband deployment, including the progress of related grant programs.
  - d. How to use broadband to advance consumer welfare, civic participation, public safety and homeland security, community development, health care delivery, energy independence and efficiency, education, worker training, private sector investment, entrepreneurial activity, job creation, and economic growth, and other national purposes.
- E. **Network Neutrality:** In August 2008, FCC adopted an Order requiring Comcast to end discriminatory network management practices, finding that Comcast's management of its broadband Internet networks contravened federal policies that protect the open nature of the Internet.
- F. **Multilateral Affairs:** The Government of the United States and the Government of Japan will continue to participate in the discussion at the ITU on the issue of network externality premium, with a view to ensuring consistency with other international agreements.
- G. **Inter-carrier Compensation:** Following adoption of the CALLS Order in May 2000 addressing inter-state access charges, the Government of the United States has, since 2005, been considering new rules for various forms of intercarrier compensation. The Government of the United States recognizes the complexity inherent in maintaining different kinds of access charges: reciprocal compensation, intra-state access charge and inter-state access charges, and is working towards establishing a unified intercarrier compensation regime with a view to rationalizing multiple charging mechanisms.
- H. **Universal Service:** In November 2008, FCC issued the Notice of Proposed Rulemaking (NPRM) seeking comment on Comprehensive Universal Service Reform, with publishing Draft Order, but it has not been adopted. In April 2009, FCC adopted the Notice of Inquiry (NOI) proceeding to create the "National Broadband Plan" including the ways for the Universal Service Programs to address broadband deployment. In this Inquiry, initial comments and reply comments are expected to be received by mid-July 2009.

## **XVI. INFORMATION TECHNOLOGY (IT)**

### **A. Protection of Copyright and Related Rights**

1. The Governments of the United States and Japan agree on the importance of protection for and enforcement of copyrighted works.
2. The Government of the United States recognizes the importance of the protection of live performances, unfixed works, and moral rights. The Government of the United States understands that the protection of these rights is important to the Government of Japan.
  - a. *Protection of Live Performances and Unfixed Works:* The Government of the United States recognizes that TRIPS Article 14 and WPPT Article 6 provide for the protection for unfixed live performances. The Government of the United States will ensure transparency regarding the protection for unfixed live performances.
  - b. *Protection of the Moral Rights of Authors and Performers:* The Government of the United States will ensure transparency regarding protection for moral rights under Federal and State law.
  - c. *Rights of Broadcasting Organizations:* The Government of the United States recognizes the Government of Japan's interest in the rights of broadcasting organizations. The Government of the United States exchanged information with the Government of Japan and will continue discussions with the Government of Japan about the rights of broadcasting organizations under U.S. law.

### **B. Response to Digital Networking**

1. The Government of the United States recognizes that the efficient exploitation of online of copyrighted works is important. The Government of the United States is constantly considering appropriate measures to facilitate the online exploitation of copyrighted works while ensuring adequate protection of their copyright, including through legislative measures.
2. The Government of the United States recognizes the importance of providing for exclusive rights in the digital environment, including the reproduction, public performance and distribution rights, in a manner that facilitates authorized use. Overlapping application of these rights causes concern for the Government of Japan that the usage of copyrighted works online is being impeded. One step taken in this regard is the November 2008 Interim Rule for Section 115 of the U.S. Copyright Law, promulgated by the U.S. Copyright Office, that clarifies the scope and application of the Section 115 compulsory license to make and

distribute phonorecords of a musical work by means of digital phonorecord deliveries.

3. The Government of the United States recognizes the importance of the right of making available. The United States has implemented the making available right through a combination of public performance, public display, distribution, and reproduction rights. The Government of the United States will ensure transparency regarding the making available right and continue to discuss this issue with the Government of Japan.
4. The Governments of the United States and Japan share the common issue of copyright infringement associated with continued advancements in digital and network technologies. The Governments of the United States and Japan will exchange appropriate and timely information regarding this issue.

## **XVII. MEDICAL DEVICES AND PHARMACEUTICALS**

The Government of the United States and the Government of Japan have discussed the Government of Japan's recommendation regarding the protection of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products.