SIXTH REPORT TO THE LEADERS ON THE
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE
June 6, 2007

The U.S.-Japan Regulatory Reform and Competition Policy Initiative, launched in June 2001, is now completing its sixth year. The Initiative was established as a bilateral forum to promote economic growth through regulatory reform. Each year, the Initiative addresses a broad range of sectoral and cross-sectoral issues, and outcomes are reported on an annual basis through the Initiative's Report to the Leaders.

The Initiative is based on the principle of a two-way dialogue between the Governments of the United States and Japan.

Following the December 2006 exchange of recommendations between both Governments, Working Groups established under this Initiative met to discuss reform in key sectors and areas such as intellectual property, distribution, privatization of public entities, information technology, competition policy, trade and investment-related measures, commercial law, telecommunications, consular affairs, and medical devices and pharmaceuticals. A High-Level Officials Group also met in April 2007 to further 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 as well as clarify measures to be taken in the future that respond to recommendations raised by each Government.

This Sixth Report to the Leaders demonstrates progress made across a wide array of issues, including reforms that will help speed regulatory decisions, heighten transparency, improve market access, enhance competition, lower barriers to business, and protect personal information. The Report also reflects joint measures to combat the problem of counterfeiting and pirated goods as well as to promote the implementation of higher regulatory and other transparency standards throughout the Asia-Pacific region. The two Governments affirm their determination to continue to increase cooperation in bilateral, regional, and multilateral fora.

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 the measures contained in this Report.

REGULATORY REFORM AND OTHER MEASURES BY THE GOVERNMENT OF JAPAN

The Government of Japan, under the Abe Cabinet's basic policy that aims to energize economic growth through innovation and openness, is accelerating structural reforms and engaging in policies that include the recommendations of:

- The Council on Economic and Fiscal Policy's (CEFP) "Course and Strategy for the Japanese Economy" (January 2007), which provides a roadmap for a new "creation and growth;"

- The CEFP's "Program for Enhancing Growth Potential" (April 2007), which seeks to boost productivity since it is key for creating a greater growth potential;

- The Council for the Asia Gateway Initiative's "Asia Gateway Initiative" report (May 2007), which envisions Japan as a gateway to bridge Asia and the world and seeks to incorporate the vitality and economic development of Asia;

- The Innovation 25 Strategy Council's "Innovation 25" report (May 2007), which is a long-term strategy for realizing sustainable growth and an affluent society through innovation and seeks to comprehensively advance both social system reforms and strategic research and development; and

- The Council for the Promotion of Regulatory Reform's (CPRR) First Report (May 2007), which provides the plan for regulatory reform over the next three years.

The Government of Japan will continue to actively advance regulatory reform, taking into account discussions by the CEFP and the CPRR and the recommendations of the "Asia Gateway Initiative" report and "Innovation 25."

I. TELECOMMUNICATIONS

A. Promotion of Competition

1. The Government of Japan has implemented a competition policy in the telecommunications field in line with rapid advances of technology, and has thereby facilitated the development of telecommunications markets where broadband services rank among the fastest, most affordable, and most technologically advanced in the world. In Japan, fiber to the home (FTTH) service as a proportion of broadband Internet subscriptions has been increasing, the number of subscribers to FTTH service exceeded 7.9 million as of the end of December 2006, as has the average transmission speed of such services. Moreover, the number of subscribers to third generation mobile phones and that of subscribed internet protocol (IP) telephony exceeded 69 million and 14 million respectively as of the end of March 2007.

2. The Ministry of Internal Affairs and Communications (MIC) set up the "Study Group on a Framework for Competition Rules to Address the Transition to IP-Based Networks" in October 2005, and published the report finalized by the study group in September 2006. On the basis of the recommendation of the

report, MIC formulated a roadmap of measures to be implemented by the early 2010's titled the "New Competition Promotion Program 2010" which includes: 1) review of designated telecommunications facilities system (dominant regulations); 2) review of calculation method for interconnection charges; 3) establishment of interconnection rules concerning the next-generation networks (NGNs); 4) competition promotion in the mobile communications market; 5) network neutrality; and 6) the review of the universal service system. MIC is advancing this program.

3. MIC is promoting further competition in the mobile communications market through various policies, including:

   a. Based on the revised rules for Telecommunications Numbers, which was enforced on November 1, 2006, the Mobile Number Portability system was initiated on October 24, 2006.

   b. In February 2007, "Guidelines Concerning Applications of the Telecommunications Business Law and the Radio Law Pertaining to Mobile Virtual Network Operators (MVNO)" were revised to promote market entry into the MVNO business. The revised guidelines clarify the application of Telecommunications Business Law to MVNOs when they propose interconnection as well as utilize wholesale telecommunication services.

   c. In November 2005, MIC assigned a spectrum for new mobile communications carriers, and a new mobile communications carrier began to provide services in March 2007.

   d. In January 2007, MIC established the Mobile Business Study Group, which will verify the factors facilitating changes in the market environment of the mobile business and recommend measures for creating new markets through invigoration of mobile business.

4. In accordance with the "New Competition Promotion Program 2010," in April 2007 MIC released the Guideline for Application of the Competition Safeguard System, intended to periodically check the validity of the scope of designated telecommunications facilities and comprehensive fair competition requirements concerning the NTT Group (including those related to the regulatory frameworks pertaining to authorization of business activities using facilities, technologies or staff of NTT East and NTT West). The first review under this Safeguard System will be conducted during Japan FY2007.

5. In March 2007, a Study Group considering the future concept of the universal service system adopted an agenda that covers the scope and providers of universal service in the future, cost calculation methodology, and contribution methodology, in accordance with the transition to IP-based networks.

B. **Fixed Interconnection**

1. Long-Run Incremental Cost (LRIC): Taking into consideration opinions submitted through the public comment procedure and the report from the Information and Communications Council, regarding interconnection rates applicable in FY2007 on the basis of the LRIC Model, MIC revised the Rules for Interconnection Charges in February 2007. In March 2007, MIC authorized interconnection rates calculated based on the revised rules, which began to be applied in April 2007. As a result, GC interconnection was set at 4.69 yen per 3 minutes, a decrease of 7.1 percent compared to the previous fiscal year; and IC interconnection was set at 6.55 yen per 3 minutes, a decrease of 4.2 percent compared to the previous fiscal year.

2. Next-Generation Network (NGN): Based on the New Competition Promotion Program 2010, MIC will begin examination of interconnection rules for the NGN keeping in mind full-fledged commercial launch of such services.

3. FTTR (Fiber to the Remote terminal): In January 2007, MIC authorized interconnection tariffs of NTT East and West to allow interconnection at poles, for providing VDSL services, in accordance with revision of the notification under Regulations for Telecommunications Facilities for the Telecommunications Business, after a public comment procedure.

4. Universal Service: Based on the profit and loss statement concerning activities for providing universal telecommunications services publicized by eligible telecommunications carriers (NTT East and West) MIC approved the universal service subsidies and the contributions applied by Universal Telecommunications Service Administrative Agency in November 2007. The amount of the contributions of interconnecting telecommunications carriers was determined to be approximately 7 yen per month per telecommunications number that each carrier has in operation.

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. MIC was notified in March 2007 that the rate would be revised downward by 2.7% compared to the previous fiscal year for interconnection within the same NTT DoCoMo service area, and by 2.3% compared to the previous fiscal year for interconnection with a subscriber located in a distant NTT DoCoMo service area.

D. **Promotion of Advanced Technologies and Services**

1. The Information and Communications Council reported Technical Requirements for the 5GHz Band Wireless Access System to MIC in December 2006, including for license-exempt use. In April 2007, the Council reported on the revision of the related ordinances for introduction of high-speed wireless local area network (LAN).

2. The Information and Communications Council reported technical requirements for broadband wireless access systems using the 2.5GHz band in December 2006 and April 2007. In May 2007, MIC solicited public comments on its proposed license policy for broadband wireless access

systems, including eligible systems and other eligibility requirements for applicants.

E. Promotion of Trade in Telecommunications Equipment

1. Conformity Assessment:

   a. In February 2007, the Governments of the United States and Japan concluded negotiations and signed a Mutual Recognition Agreement (MRA) relating to conformity assessment of telecommunications equipment.

   b. In February 2007, the Governments of the United States and Japan also exchanged letters regarding an arrangement that would permit acceptance of results of conformity assessment for information technology (IT) equipment and industrial, scientific and medical (ISM) equipment conducted by accredited Japanese conformity assessment bodies with respect to Electro-Magnetic-Compatibility (EMC).

2. Type Approval: MIC is preparing for new rules for wireless LANs that allow additional antennas to be approved for a product under the same certification number.

II. INFORMATION TECHNOLOGIES (IT)

A. IT and e-Commerce Policymaking

1. IT Policy Plans: On April 25, 2007, the Council on Economic and Fiscal Policy released the Program for Enhancing Growth Potential, which includes further measures to promote IT innovation. The IT Strategic Headquarters (ITSH) is planning to release a new IT Priority Policy Program (Program) in summer 2007. The ITSH provided a public comment period for a draft of the Program and will consider the comments it receives. The Government of Japan will continue to promote and implement its major IT policy plans, including the New IT Reform Strategy and the Program, in a manner that fosters private-sector leadership and active participation in policymaking processes.

2. Private-Sector Input: The Government of Japan understands that it is important to seek and consider a diverse range of opinions from the private sector when creating and implementing IT and e-Commerce policies. IT policy plans such as the IT Strategy have been developed and evaluated by the ITSH and the Expert Committee on IT Strategy Evaluation, which includes members from the private sector. In addition, the ITSH has sought various opinions from interested parties, including in the private sector, by employing public comment procedures. The Government of Japan will continue to provide meaningful opportunities for interested parties in the private sector to give input at early and subsequent stages in the formulation of IT and e-Commerce polices.

3. Technology Neutrality: In the 2005 and 2006 Report to the Leaders, the Government of Japan shared the view with the Government of the United States that it is generally important to implement laws, regulations, and guidelines related to IT in a manner that strives not to unduly promote, mandate, or favor specific technologies (technology neutrality), in order to provide maximum flexibility and encourage innovation in the private sector. The Government of Japan will continue to apply this perspective. In addition, the Government of Japan will cooperate closely with the private sector in international standards development activities and give consideration to established international standards in the implementation of its IT policies.

4. International Compatibility: The Government of Japan understands that it is important to foster an environment that further promotes cross-border e-Commerce. The Government of Japan will continue to seek to harmonize policies and legal frameworks on e-Commerce and related Internet technologies with international practice.

B. Strengthening the Protection of Intellectual Property Rights (IPR)

1. Enforcement System:

   a. *Statutory Damages*: The Government of Japan will continue to consider further measures to strengthen protection of copyright and decrease the burden on right holders, including through the availability of a pre-set statutory compensation system for infringement, and will reach a conclusion of its review in this regard by the end of FY2007 as stated in the 2006 Intellectual Property (IP) Strategic Program.

   b. *Copyright Term Extension*: The Government of Japan will continue its deliberations on extending the terms of protection for copyrighted works, in consideration of relevant factors including global trends and the balance between right holders' and users' benefits, and will reach some degree of conclusion of its review of the terms of copyright by the end of FY2007 as stated in the 2006 IP Strategic Program. The Government of Japan recognizes the Government of the United States' concern that any extension of the term of protection for sound recordings be in parity with all copyrighted works.

   c. *Ex officio*: The Government of Japan is considering what an appropriate system for investigation and prosecution for copyright crimes should be, including whether the requirement of the complaint of the injured person (right holder) might be a substantial obstacle to penalize copyright crimes. The Government of Japan will reach some degree of conclusion of this review by the end of FY2007.

   d. *Book Piracy*: The Government of Japan will continue to discuss the issue related to the unauthorized reproduction of books, especially on university campuses with the Government of the United States, and will also discuss the impact of exceptions to copyright protection on

scientific, technical and medical publishing as well as any possible new exceptions.

e. *Movie Piracy*: A bill which makes it possible to punish those who make sound or visual recordings of movies in movie theaters, even if the recordings are for the purpose of private use, by applying the penalty provision of the Copyright Law, passed the Diet on May 23, 2007.

2. Protection of Digital Content: The Government of Japan has made appropriate internal regulation and decrees to forbid copyright infringement in its governmental operations that address the misuse of file-sharing technologies and protect IP, software and other digital content assets used. The Government of Japan will continue to exchange information on this issue with the Government of the United States.

The Government of Japan will continue to apply its private reproduction exception in a manner consistent with its international agreements. The Government of Japan will also continue to update the Government of the United States about its study of "access controls."

3. IP Multicasting Statutory License: The Government of Japan has confirmed that the revision was done within the minimum necessary scope in order to smoothly introduce simultaneous retransmission through IP multicasting with due consideration paid to copyright protection and that this amendment is in compliance with the WCT and WPPT. The Government of Japan acknowledges the importance the Government of the United States assigns to market-based solutions for emerging technologies and business models.

4. Private-Use Exception: The Government of Japan has confirmed the existence of the right of making available to address the infringement of copyrights and neighboring rights in works and phonograms that are uploaded onto peer-to-peer networks. The Government of Japan has confirmed that this is in compliance with the WCT and WPPT. In addition, the Government of Japan will continue to make efforts to clarify its interpretation of the scope of the private reproduction exception considering provisions of related international agreements and technological developments.

5. Education Exception to Copyright Law: The Government of Japan has issued guidelines and presented examples of the "educational exceptions" in the Copyright Law for educational institutions, teachers, and students to clarify the limitations of the exception under the amended Copyright Law. The Government of Japan will continue to discuss with the Government of the United States limitations to the exceptions on this issue, with a view toward identifying any issues related to the unauthorized reproduction of books and journals.

6. Patent Procedures:

a. *Deferred Examination System*: The Government of Japan will continue to discuss information regarding usage of the 3-year deferred examination system with the Government of the United States.

b. *Patent Application Prosecution*: The Government of Japan will exchange, with the Government of the United States, information regarding effective means to promote work share efficiencies in the examination process.

7. Trademarks: The Government of Japan will discuss Japan's practices regarding protection of geographical indications with the Government of the United States.

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

1. The Governments of Japan and the United States have been closely cooperating to strengthen IPR protection and enforcement around the world. The Government of Japan will continue to use Asia-Pacific Economic Cooperation (APEC) as the primary forum in which to closely cooperate with the Government of the United States on strengthening IPR protection and enforcement in the Asia-Pacific Region, and to cooperate in all other appropriate international fora, including the World Trade Organization (WTO), to advance protections for IPR.

2. Japan-U.S. cooperation has achieved numerous results such as the APEC Anti-Counterfeiting and Piracy Initiative and its five model guidelines which will be advanced to ensure strong deliverables in APEC this year, the Joint Department of Commerce – Ministry of Economy, Trade and Industry (DOC-METI) Initiative, WTO TRIPS transparency request to China, and Japan's request for participation as a third party in the WTO consultation requested by the United States regarding China's measures on IPR protection and enforcement.

3. At the Japan-U.S summit held in April 2007, the Governments of Japan and the United States affirmed their common position to strengthen Japan-U.S. cooperation on IPR issues. The Government of Japan will continue to cooperate with the Government of the United States in bilateral, regional, and multilateral fora to promote greater protection for IPR world wide.

4. The Government of Japan will continue to discuss with the Government of the United States the idea introduced by then Prime Minister Koizumi at the G8 Gleneagles Summit in July 2005 regarding a possible international agreement to address the proliferation of counterfeit and pirated goods.

D. **Promoting Online Security**

1. Privacy: The Act on the Protection of Personal Information (Act) went into effect in April 2005. Based on the Act, which outlines the minimum acceptable parameters for all industrial sectors, Ministries have formulated industry-specific guidelines. The Government of Japan regards it as essential

to ensure transparency, respect voluntary efforts by the private sector, and promote better understanding by entities, concerning the implementation of the Act. The Basic Policy of the Act stipulates that the Cabinet Office will examine the implementation status of the Act approximately three years after it went into effect and will take necessary measures based on the results. The issues concerning personal information protection have been discussed in the Quality-of-Life Policy Council (Council), which has held multiple rounds of hearings with industry, private institutions, relevant ministries, non-profits and academics. The Council plans to release a document (Report) in summer 2007, reviewing the Act's effectiveness and potentially recommending measures to improve implementation.

a. In February 2007, the Cabinet Office added to the list of guidelines on their website a notation explaining that non-compliance with the provisions encouraging voluntary efforts will not result in penalties prescribed by the Act, while the provisions strongly urge entities to make efforts to comply.

b. In June 2006, the Cabinet Office compiled the reports from the relevant Ministries and Agencies about the implementation status of the Act in fiscal year 2006 and publicly announced its summary. The Cabinet Office will continue to make an effort to provide details to better educate companies how to comply with the Act.

c. The Government of Japan is making efforts to ensure the transparent, consistent, and effective review of the implementation of the Act. The Council arranged and publicly announced "The Main Agendas Concerning the Personal Information Protection" in July 2006, followed by a voluntary public comment period. To make the Council's review as effective and transparent as possible, the Cabinet Office has created new pages on the Council's website disclosing its meeting schedules and minutes, as well as soliciting public comments and issuing comments received. The Council will continue its discussions and deliberations, and compile its report in summer 2007.

d. Recognizing the importance of ensuring protection of personal information, accountable but efficient cross-border data flows, and the value of a flexible privacy approach, the Governments of the United States and Japan participate in multilateral fora to exchange information and generate consensus on issues such as privacy.

2. Online Nuisance, Deceptive Practices, and Fraud: The Governments of Japan and the United States are concerned with spam, phishing, and other forms of online fraud that negatively impact businesses and consumers, and interfere with the adoption and smooth functioning of IT and e-Commerce. Along with generating substantial costs throughout society, these online nuisances can erode essential consumer confidence in online transactions. The Government of Japan has been promoting activities aimed at addressing online nuisance and fraudulent practices.

a. The Government of Japan has been working on multifaceted anti-spam, anti-phishing, and other related measures in close cooperation with private businesses, which include Internet service providers and mobile operators.

b. The Ministry of Economy, Trade and Industry's (METI) multimedia Check PC Campaign serves as an example of Government of Japan efforts to educate consumers on the importance of taking necessary steps to protect their computers from phishing attacks and other forms of online nuisance.

c. The Government of Japan has been vigorously enforcing its Law on Regulation of Transmission of Specified Electronic Mail (the Anti-Spam Law) and publishing information on arrests under the Law on the websites of the National Police Agency (NPA) and prefectural police. The prefectural police have issued press releases about these cases.

d. The Ministry of Internal Affairs and Communications (MIC) has been helping increase private sector understanding of how the Constitutional Secrecy of Communications provisions and the Telecommunications Business Law impact the way technological firms and Internet service providers can develop and use new technologies to filter and block spam in Japan. In this endeavor, MIC has created websites in English to explain the legal matters concerning the introduction of these anti-spam technologies.

e. Japan and the United States were among the first signatories on the Council of Europe Convention on Cybercrime (Convention). The United States ratified the Convention on September 29, 2006; the Japanese Diet approved the conclusion of the Convention in April 2004. The Government of Japan will conclude the Convention as soon as the bill to amend the domestic laws necessary to implement the Convention is passed by the Diet.

f. As online nuisance and fraudulent practices including spam and phishing are global in nature, the Government of Japan will strengthen cooperation with the Government of the United States through continued exchange of information, taking advantage of the frameworks of international organizations such as the Organisation for Economic Cooperation and Development (OECD) and APEC as well as bilateral consultations. An example of our productive collaboration is the work by the U.S. Federal Trade Commission and the relevant authorities of Japan in the context of the International Consumer Protection and Enforcement Network (ICPEN) to translate the E-consumer.gov website into Japanese to help educate consumers. The Governments of the United States and Japan will continue to share information and experiences to improve best practices regarding spam, phishing, and online fraud.

3. Government Information Security: When new IT security policies or standards are determined regarding the procurement of information systems, the Government of Japan will take into consideration the consistency among its ministries and agencies, as well as between central and local governments, and release the draft for public comment procedure according to its necessity and contents.

E. Health IT and e-Accessibility

1. Health IT: On March 27, 2007, the Ministry of Health, Labour and Welfare (MHLW) released the final version of a new "Grand Design for the Use of Information Technologies in the Medical, Healthcare, Nursing, and Social Welfare Fields" (new Grand Design), which builds on the previous Grand Design created in 2001.

   a. The new Grand Design indicates that beginning in fiscal year 2007, MHLW will support efforts to verify the interoperability of different health IT systems, make the results of this verification process public, and promote the spread of health IT systems that adopt certain standards. In the field of health IT, the Government of Japan will continue to make utmost efforts to ensure that technology neutrality is maintained within a proper and practical scope. In addition, MHLW will continue to provide information about activities such as the interoperability verification process in a timely and open manner, including by posting this information on its website, to help all interested parties understand and fully participate in them.

   b. MHLW offered a public comment period (February 13 to March 2, 2007) for a draft of its new Grand Design and posted comments received on its website. The Government of the United States appreciated this opportunity for it and other interested parties to provide input on this important plan. The Government of Japan takes note of the view of the Government of the United States that although a draft of the Grand Design was not subject to public comment procedures as stipulated in the Revised Administrative Procedure Act, a public comment period of at least 30 days would have helped ensure that interested parties had sufficient time to provide input.

   c. METI is committed to posting information about procurements for government-sponsored projects on its website and accepting participation in them by a wide range of qualified vendors. To help ensure that qualified vendors could contribute to the success of a project to create a medical information network in the Tokai region of Japan that METI began to sponsor in fall 2006, METI posted information about the procurement for the project on its website in May 2006. In addition, METI posted information about the progress of this project on its website in March 2007. Ministries will continue to post information about government-sponsored projects used to develop or showcase health IT systems on their websites prior to fully launching projects or soliciting participation in them.

2. e-Accessibility: The Government of Japan understands that it is important to reduce the digital divide concerning age and physical disability. Relevant Ministries and Agencies have developed domestic standards, promoted international standardization activities and promoted appropriate measures including support and aid projects. The Governments of Japan and the United States have been exchanging views on current and future e-accessibility policies and activities in an effort to enhance the understanding of our approaches to accessibility. The Governments of the United States and Japan will deepen the exchange of information, using methods such as video conference or by meeting when experts visit each other's countries on other business, as appropriate.

F. **Government IT Procurement Reforms**: On March 1, 2007, the Inter-Ministerial Chief Information Officer Council (CIO Council) released the "Basic Policy for the Public Procurement of Computer Systems" (Basic Policy). When the Basic Policy becomes effective on July 1, 2007, the CIO Council will ensure that its members and other government procuring authorities fully adhere to it. MIC will compile and distribute a manual (*jitsumu tebikisho*) that will help procuring entities better understand how to implement the Basic Policy. Each fiscal year, the Cabinet Secretariat will conduct "follow-up" surveys designed to measure progress made in implementing the Basic Policy and to help determine whether it should be revised. In the past, the Inter-Ministerial Task Force for Information Systems Procurement (Task Force) publicized the results of the follow-up surveys conducted on the implementation status of the Task Force memorandum of agreement.

1. The Basic Policy stipulates that government procuring authorities will set appropriate limits on, and clearly define, liability in government IT procurement contracts. The Basic Policy also stipulates that to help them accomplish this goal, government procuring entities will solicit advice from legal experts.

2. Based on the Intellectual Property Strategic Program 2006, the Government of Japan submitted to the Diet a bill amending the Industrial Technology Enhancement Act, which makes it possible for contractors to possess intellectual property rights concerning software developed through government-sponsored programs. The Diet passed this bill on April 27, 2007.

3. Based on the Basic Policy, the information that government procurement authorities are required to contribute without delay to the Government of Japan's online database for information systems procurement (Database) is to be expanded to include items such as procurement plans, specifications for procurements, and information on announcements for bids. The Government of Japan will move forward as quickly as possible in its efforts to study how to analyze information in this improved Database to help identify and monitor trends in IT procurements such as changes in the percentage of procurements using competitive and sole source contracts and the number of contracts using multi-year Treasury obligations and the Overall Greatest Value Method, and how to release the results.

4. In accordance with the notice "Promoting Proper Public Procurement" (Ministry of Finance No.2017, August 25, 2006), Ministries have publicized information such as contractors' names, values of contracts, and justifications for sole source IT procurement contracts (as well as non-IT contracts) on the website of each Ministry. In addition, Ministries reviewed justifications for sole source contracts and determined to generally shift from these contracts to competitive bidding, except for contracts for which a substantially justified reason was provided. These justifications are publicized on Ministries' websites. The Basic Policy notes that Japan's 1947 Public Accounts Law, as well as other laws and regulations, have established the principle that procurements should be conducted through competitive bidding processes. The Government of Japan will continue its efforts to ensure that this principle is fully incorporated into its IT procurement practices.

5. The Basic Policy stipulates that contracts should be swiftly concluded after winning bidders are chosen and prohibits the backdating of contracts.

6. MIC provided a public comment period (December 23, 2006 to January 18, 2007) for a draft of the Basic Policy and posted comments received on MIC's website. In addition, MIC held a public briefing session on the Basic Policy on January 11, 2007. The Government of Japan will continue to provide meaningful opportunities for interested parties to advocate, and participate in the formulation of, proposed changes to the Basic Policy.

III. MEDICAL DEVICES AND PHARMACEUTICALS

A. **Changes in the Japanese Healthcare System:** In FY2006, the Japanese Government proposed healthcare changes through the New Health Frontier Strategy and Innovation 25 program, and private-sector members of the Council on Economic and Fiscal Policy proposed reforming drug R&D, clinical trials, reviews, and pricing. As the Ministry of Health, Labour and Welfare (MHLW) and advisory bodies such as *Chuikyo* consider and implement changes in Japan's healthcare system, industry, including U.S. industry, may express views to MHLW, which will give them consideration. In January 2007, Japan began a Government-Private Sector Dialogue for Innovative Drug Discovery to enhance the competitiveness of its drug industry. The Dialogue includes the Minister of Health, Labour and Welfare, Minister of Economy, Trade and Industry, and Minister of Education, Culture, Sports, Science and Technology, and representatives from the drug industry, the National Center for Advanced and Specialized Medical Care (National Center), and academia. U.S. industry participated in the Dialogue meetings in January and April 2007, and these meetings will be held periodically. Representatives from the above-mentioned ministries, the medical device industry, National Center, and academia participate in a Government-Private Sector Dialogue to enhance the competitiveness of Japan's medical device industry, which Japan began in April 2007.

B. **Medical Device and Pharmaceutical Pricing Reform and Related Issues:** MHLW will consider rewarding development of innovative medical devices and pharmaceuticals by taking the following actions on reimbursement pricing in FY2007 (unless another year is shown):

1. Pharmaceuticals:

   a. *Chuikyo*: MHLW will continue to select suitable candidates, irrespective of nationality, to serve as members of *Chuikyo*'s Drug Pricing Expert Subcommittee.

   b. *Drug Pricing Organization*: Before meeting with the Drug Pricing Organization (DPO), MHLW will have the Economic Affairs Division provide explanations sufficiently in advance to industry, including U.S. industry, ensuring that those points currently being considered by the Health Insurance Bureau are properly explained.

   c. *Pricing Reform Proposals*: MHLW will provide industry, including U.S. industry, with opportunities to express its views on proposals to reform Japan's drug pricing system, and will consider those views.

   d. *Rewarding Innovation*: MHLW will discuss with industry, including U.S. industry, ways to improve the reward for innovation. Such discussions will include examining the effect on drug innovation of recent changes in the Foreign Price Adjustment rule and of the extent of MHLW's use of premiums.

   e. *Annual Price Revisions*: MHLW will continue to ensure that if *Chuikyo* discusses the issue of the frequency of reimbursement price revisions, it will provide industry, including U.S. industry, with opportunities to provide input to MHLW and *Chuikyo*. MHLW notes that the U.S. Government expressed its strong opposition to any system by which the reimbursement prices of pharmaceuticals and medical devices can be changed every year.

   f. *Re-Pricing Criteria for Market Expansion*: MHLW will continue to discuss with industry, including U.S. industry, the issue of re-pricing criteria for market expansion.

   g. *Data Protection Period*: On April 1, 2007, MHLW extended the standard length of the reexamination period for medicines with new active ingredients from 6 years to 8 years. During the reexamination period of a drug, approval applications of drugs with the same active ingredients must be supported by the full data required of a new drug application. This measure, in effect, extends the data protection period.

   h. *Distribution*: Five members of the Marketing Committee of the Japan Pharmaceutical Manufacturers Association (JPMA), including representatives of foreign firms, participate in the Council for Improvement in the Distribution of Ethical Drugs (*Ryukaikon*). MHLW continues to provide industry, including U.S. industry, with opportunities to express its views.

2. Medical Devices:

a. *Foreign Average Price (FAP) Rule for Medical Devices*: MHLW continues to provide industry, including U.S. industry, with opportunities to express its views on the medical device pricing issues, including 1) elements of the Foreign Average Price (FAP) rule, such as the number of functional categories to which the rule is applied, maximum price-cut rules, and data used in price calculations, and 2) the Asian study commissioned by *Chuikyo*.

b. *Functional Categories*: MHLW will continue to discuss with industry, including U.S. industry, increasing functional categories to reflect differences in technology, performance, and clinical benefits of devices.

c. *C1 and C2 Pricing*: MHLW will be open to discussing proposals from industry, including U.S. industry, on C1 and C2 pricing procedures.

d. *Diagnostic Imaging*: MHLW will continue to evaluate properly advanced diagnostic imaging equipment and techniques.

e. *In-Vitro Diagnostics*: In 2007, MHLW and the in-vitro diagnostics (IVD) industry, including U.S. industry, formed a study group (*benkyokai*) to discuss IVD-related issues, including IVD reimbursement fee and review rules. MHLW continues to provide industry, including U.S. industry, with opportunities to express its views on IVD issues.

3. Blood Products: MHLW will be open to discussing with industry, including U.S. industry, pricing issues related to blood products.

C. **Medical Device and Pharmaceutical Regulatory Reform and Related Issues**: Innovative medical devices and drugs often are introduced in Japan years after the United States and Europe. The Japanese Government intends to eliminate these lags by strengthening R&D, stimulating clinical trials, and streamlining reviews. MHLW will improve its regulatory system by taking the following actions in FY2007 (unless another year is shown):

1. Pharmaceuticals:

a. *PMDA Expansion*: MHLW will ensure the Pharmaceuticals and Medical Devices Agency (PMDA) achieves its target of increasing the number of reviewers (193, as of October 1, 2006) by 236 people by March 31, 2010. PMDA plans to hire 58 new reviewers in FY2007, 80 in FY2008, and 98 in FY2009. User-fee increases effective April 1, 2007, will fund hiring of the new reviewers. The new reviewers will have expertise in many fields. MHLW and PMDA will continue to exchange views on PMDA's status of performance with interested parties, including the U.S. pharmaceutical industry.

b. *Simultaneous Global Development of Pharmaceuticals*: To promote simultaneous global development of medicines, MHLW published the draft guidelines clarifying Japan's regulations of global clinical trials in April 2007. MHLW and PMDA will exchange views with related parties including the U.S. pharmaceutical industry on how global simultaneous development of medicines including in Japan can be best realized.

c. *Improving the Environment for Pharmaceutical Clinical Trials*: In April 2007, MHLW announced a five-year plan to stimulate clinical trials in Japan, including an increase in clinical research staffing at a network of 10 Core Clinical Research Centers and 30 Major Clinical Trial Institutions that will play a central role in stimulating trials.

d. *Pharmaceutical Performance Goals and Metrics*: PMDA will continue to publish its goals and performance metrics. In conjunction with PMDA's staff expansion that began on April 1, 2007, PMDA established the following review performance goals to be accomplished by the end of FY2011:

(1) to reduce by 1.5 years the pre-application drug lag, and

(2) to reduce by 1 year the application review period,

thereby reducing the total period from pharmaceutical development to approval by 2.5 years, where pre-application drug lag means the period between application filing dates in Japan and the United States/EU for a medicine with new active ingredients. To achieve the goals, PMDA will provide manufacturers with up to 1,200 opportunities for clinical trial consultations according to the demand. Also by March 31, 2009, PMDA will reduce consultation waiting times from approximately 3 months to approximately 2 months. MHLW and PMDA will continue to exchange views on PMDA's performance with related parties, including U.S. industry. PMDA continues to give industry, including U.S. industry, necessary review and consultation performance data.

e. *Reducing PMDA's Pharmaceutical Backlog*: Since its establishment (April 2004), PMDA reduced its New Drug Application (NDA) backlog from 139 to 20 as of March 31, 2007. With regard to applications received since April 2004, MHLW and PMDA are making all possible efforts to ensure reviews are carried out properly and promptly and to attain the mid-term target of completing 80 percent of applications in 12 months of administrative time by March 31, 2009. PMDA will continue to make every attempt to decrease the backlog of NDAs.

f. *Committee on Issues Related to the Use of Unapproved Pharmaceuticals*: MHLW will explain to industry, including U.S. industry, the nature and operation of the system regarding the

Committee on Issues Related to the Use of Unapproved Pharmaceuticals.

g. *Pharmaceutical Manufacturing Changes*: A December 2006 notification from MHLW announced its policy of processing the following variations within the target period of three months, excluding those on new pharmaceuticals or biologics:

(1) addition of manufacturing sites necessitating no new accreditation of foreign manufacturing sites, and

(2) addition or change of manufacturing sites with minor changes to manufacturing methods.

MHLW and PMDA will exchange views on these issues with industry, including U.S. industry.

h. *Vaccines*: In March 2007, MHLW published a report, "Vision for the Vaccine Industry" (Vaccine Vision), to help develop and supply vaccines needed in Japan, and established a Vaccine Industry Vision Promotion Committee to carry forward the Vaccine Vision, including its Action Plan. Representatives of Japanese and foreign industry serve on the committee. MHLW will continue to assist in developing vaccines necessary for public health by promoting exchanges of views in the committee among interested parties, including U.S. industry. MHLW will exchange views on regulatory requirements for vaccines with industry, including U.S. industry.

2. Medical Devices:

a. *Medical Device Reviewers*: MHLW will ensure PMDA attains its midterm goals of increasing medical device reviewers and ensuring they are experts in their areas of responsibility. MHLW will ensure that PDMA increases by 8 the number of medical device reviewers (27, as of November 1, 2006) by March 31, 2009.

b. *Medical Device Application Backlog*: PMDA has already eliminated almost 90% of the backlog of medical device applications that existed at the time of its establishment. PMDA will continue to make every attempt to decrease the backlog of medical device applications.

c. *Medical Device Clinical Data*: MHLW's policy is to accept foreign clinical data to the greatest extent possible. MHLW issued a notification on March 31, 2006, explaining that data from foreign clinical trials are accepted if the trials are carried out according to the standards equivalent or superior to Japanese clinical trial standards (Good Clinical Practices, or GCPs). When PMDA requires supplementary clinical trials to be carried out in Japan, it clearly explains the scientific grounds of its decision to applicants. The ICH (International Conference on Harmonization) GCPs are GCPs related

to medicines, and conformity with these is not required. It is generally accepted by MHLW that clinical trials that have been carried out according to U.S. medical device GCP regulations and are accepted by the U.S. Food and Drug Administration (FDA) are compatible with Japanese GCPs.

d. *Medical Device Partial Change Approvals*: MHLW will continue its efforts to clarify to industry which partial changes require companies to submit applications for approval and which changes require companies to simply notify PMDA. MHLW requires partial change approval for a change that is supposed to affect a device's quality, safety, or effectiveness. In February 2007, MHLW, PMDA, and industry, including U.S. industry, formed a working-level task force to address any issues of industry's concern, including the issue of defining partial changes, the issue of approval vs. notification, and the issue of allowing partial change applications while previous applications for the same device are under review. After the task force reports its recommendations, MHLW will clarify publicly the requirements for partial change approval and notification.

e. *Raw Material Data for Medical Devices*: MHLW requires only the minimum information necessary to ensure raw material safety and biocompatibility. In February 2007, MHLW, PMDA, and industry, including U.S. industry, formed a working-level task force to address this and other issues.

f. *QMS Inspections*: MHLW ensures PMDA will make its best efforts to conduct the Quality Management Systems (QMS) audits, including audits of foreign manufacturing plants, in a way that does not delay product approvals. In principle, no QMS on-site inspection is conducted at those manufacturing plants that produce constituent parts that do not by themselves constitute medical devices. With regard to the accreditation of foreign manufacturers, as a general rule, no foreign manufacturer registration is required for those entities supplying raw materials or other components.

g. *New Diagnostic Tests*: MHLW will provide opportunities to industry, including U.S. industry, to consult regarding the use of new diagnostic tests in clinical trials after a product approval application has been submitted, a mechanism available for pharmaceuticals and medical devices under certain conditions.

D. **Blood Products**: MHLW recognizes that the demand for pharmaceuticals and blood products in Japan is driven by the market corresponding to medical needs. In FY2006, MHLW initiated twice-yearly meetings with the blood products industry, including U.S. industry, on issues such as the supply and demand plan.

E. **Over-the-Counter (OTC) Medicines**

1. Revised Regulations: MHLW will formulate and implement through ministerial ordinance by June 2009 revised regulations on OTC medicine sales. MHLW will exchange views with related parties, including U.S. industry, on formulation and implementation of the revised regulations.

2. Advertising: MHLW will take into account comments from industry, including U.S. industry, on the laws and regulations affecting advertising of OTC medicines. MHLW has designated a contact point to exchange information with industry, including U.S. industry, regarding 1) MHLW's policies on promotion and advertisement of pharmaceuticals, including OTCs, and 2) the activities of the Local Advertisement Controllers' Meeting (*Rokushakyo*).

F. Nutritional Supplements

1. Educational and Informational Statements:

   a. The regulatory system for nutritional supplements in Japan has been structured to conform with guidelines published by the Joint FAO/WHO Food Standards Programme and the Codex Alimentarius Commission. MHLW will continue to give due consideration to trends in international standardization through the Codex Alimentarius Commission and will aim to ensure fairness in the Japanese system for Food with Health Claims.

   b. MHLW continues to explain the regulatory system for Foods for Specified Health Uses (FOSHU) to industry, including questions about the format required for FOSHU applications. MHLW accepts the foreign clinical data in FOSHU applications when relevant evidence gathered outside Japan is applicable to the Japanese. MHLW continues to have dialogues with and to provide opportunities for discussion to industry, including U.S. industry, to promote better understanding of the FOSHU and Foods with Nutrient Function Claims (FNFC) systems and other related issues.

   c. On the basis of the recommendations of the Office of Trade and Investment Ombudsman (OTO), MHLW is working with industry to establish a system by the end of FY2007 or earlier that can provide consumers with accurate information from the database of the Incorporated Administrative Agency of the National Institute of Health and Nutrition when consumers request such kind of information.

2. Designation of Food Additives: The Government of Japan recognizes the importance of international harmonization in the area of food additives. (Please also see section VIII.D.5 on "Safety Evaluation of Food Additives" under Other Trade-Related Government Practices on page 40.)

   a. The Government of Japan responds to questions about the application process and exchanges views with industry, including U.S. industry, on

proposals for new food additives and for revisions to the standards of use for designated food additives.

b. The Government of Japan will make efforts to proceed with the food additive designation process in the most efficient possible way.

3. Quantity Limits for Food Additives:

a. With regard to elements that are naturally occurring in food products, such as benzoic acid and sorbic acid, MHLW does not take the stance that food products are in violation of standards on the use of food additives only because they are found to contain such elements. Rather, in cases such as these, MHLW requires the importer to submit literature and data that can demonstrate to what extent the element concerned is present in the raw materials used to establish that this element is indeed naturally occurring. Decisions will be made based on the evidence submitted.

b. MHLW continues to improve the process for clearing shipments that are stopped at quarantine stations due to the detection of naturally occurring food additives, such as by offering more comprehensive prior consultations and improving the system of sharing information among quarantine stations.

4. Import Procedures:

a. With regard to the style of supplementary written documentation that importers can submit at the time of importation, as long as the documentation can show that the food product concerned is neither a medicine nor a quasi-drug as covered by the Pharmaceutical Affairs Law, MHLW confirms that there is no specific style of documentation by which this should be demonstrated. Therefore, importers do not need to use the supplemental form, which was different for each port.

b. With regard to streamlining quarantine station procedures, MHLW has made efforts to improve the systems of documentation and the sharing of information and will continue to work on improvements.

c. MHLW has increased the number of locations that offer prior consultations from six to thirteen.

5. Import Duties:

a. Most vitamin-based nutritional supplements fall under the 2106.90.295.4 HS code with a tariff of 12.5%, and many other nutritional supplements such as mineral nutrients fall under the 2106.90.299 HS code with a tariff rate of 15%. This is in contrast to when these ingredients are imported as medicines under HS categories 3003 and 3004, which have a tariff rate of zero. The Government of Japan will continue to address the issue of tariff levels including on

nutritional supplements containing the same ingredients as pharmaceuticals in WTO negotiations comprehensively.

b. The Government of Japan will continue to discuss this issue with the Government of the United States.

G. Cosmetics and Quasi-Drugs

1. Quasi-Drug Regulations:

a. MHLW will ask industry, including U.S. industry, for its views on the possibility of the publication by industry of a comprehensive list of active ingredients with their levels and product categories for medicated cosmetics. MHLW will continue to share information on this issue with the U.S. Government.

b. MHLW will continue exchanging views with industry, including U.S. industry, on regulations for quasi-drugs, such as how additives are evaluated in quasi-drug applications.

c. If there is a concrete proposal from industry to create an additional product standard, MHLW will consider it seriously.

2. Advertising and Labeling:

a. MHLW will continue exchanging with industry, including U.S. industry, views on the claims allowed for cosmetics, including those on their expansion.

b. MHLW will take into account the comments from industry, including from U.S. industry, on the development of and revision of advertising and labeling regulations for cosmetics and quasi-drugs.

c. MHLW will exchange views with industry, including U.S. industry, on the enforcement of regulations and notifications across prefectures, including on the role of the Local Advertisement Controllers' Meeting (called "*Rokushakyo*").

3. Transparency and Regulatory Procedures:

a. MHLW will consult the Council on Drug and Food Sanitation on the revision of its standard on sanitary pads and take other necessary measures, with the intent to publish and implement the revised standard by February 2008.

b. When MHLW revises the standards for approval of quasi-drugs and standards for cosmetic products, it will continue to consider opinions and requests from industry, including U.S. industry, and also will continue to explain expected timelines for revisions and implementation.

c. MHLW will continue exchanging views with industry, including U.S. industry, on how the notifications necessary to import cosmetics and quasi-drugs can be improved.

d. MHLW will continue exchanging views with industry, including U.S. industry, on reducing the lead time for the approval of quasi-drug applications.

e. MHLW will respond to questions from industry, including U.S. industry, on and clarify requirements related to safety data needed for quasi-drug applications including those related to animal testing.

f. MHLW will maintain its current efforts to update its website in as timely a fashion as possible and to disseminate detailed information on its regulatory requirements and registration procedures including new or revised regulations, notifications, and administrative memos to relevant organizations in Japan. MHLW continues to respond to specific requests from industry, including U.S. industry, to provide primarily via relevant trade associations the text of new or revised regulations, notifications, and administrative memos that neither have been posted on its website nor disseminated to relevant organizations in Japan.

IV. FINANCIAL SERVICES

A. **Increasing Competitiveness of Japan's Financial and Capital Markets**: The Government of Japan has established a number of working groups to consider how to increase the competitiveness of Japan as an international financial center. In January 2007, the Study Group on the Internationalization of Japan's Financial and Capital Markets was established under the Financial System Council in order to discuss a broad range of issues, in the light of enhancing the attractiveness of Japan's financial and capital markets as an international financial center, and in the group, domestic and foreign interested parties were provided opportunities to express their opinions. The United States welcomes the efforts made by the Government of Japan to improve the competitiveness and attractiveness of Japan's financial and capital markets and recommends continued dialogue among all interested parties.

B. **Specific Measures**

1. Creating a Legal and Regulatory Framework for a Credit Bureau System: The revision of the Money Lending Business Law passed in December 2006 calls for expansion of the use of credit information and mandatory use of lenders' exchanges by consumer finance companies. Through lenders' exchanges of various types of consumer finance companies, the Financial Services Agency (FSA) is working to require that full-file credit information with respect to credit exposures of consumer finance companies is available, so that they can have more information on which to base their credit analysis.

2. Firewalls: The Council on Economic and Fiscal Policy (CEFP) and the

Financial System Council discussed the barriers between banks and securities companies, so called 'firewalls regulation.' In response to this discussion, the Financial System Council will sufficiently examine the 'firewalls regulation' considering the points of view such as an achievement of effective office administration within a financial group, the ability of financial groups to best serve customer needs, appropriate information sharing within a financial group for effective risk management, competition issues (e.g., preventing abuses of dominant bargaining position by banks toward companies), and preventing potential conflicts of interest between banks and securities companies.

The FSA published Guidelines for the Regulation of Conglomerates in June 2005, and revised those Guidelines in July 2006 and March 2007. The FSA recognizes that regulation of conglomerates, including permissible management structures and the ability to share information across group companies for prudential risk management and improved customer service are items relevant to Japan's efforts to increase its competitiveness as an international financial center. As such, considering the arguments of the CEFP and Financial System Council, the FSA will continue to consult with interested parties, including foreign financial firms, regarding the implementation of the Conglomerate Guidelines.

3. Defined Contribution Pensions:

a. The Government of Japan recognizes the importance of, and the value of improving, the national defined contribution pension system in terms of securing income for the elderly, labor mobility, and investment education. From October 2006, the Ministry of Health, Labour and Welfare (MHLW) established a Corporate Pension Study Group, made up of experts in the field, and is examining the current situation on the functioning of the corporate pension system in the Study Group.

b. The Study Group is discussing various issues including the defined contribution pension system about the tax deductible contribution limit, employee contributions, early access to funds before the age of 60 in specified circumstances, and investment advice to be made available to participants.

c. At the third meeting of the Corporate Pension Study Group, held on November 27, 2006, interviews were carried out with related parties, including the American Chamber of Commerce in Japan (ACCJ), as to their requests and opinions regarding how best to improve the defined contribution pension system.

d. Further, the Proposal for the Unification of the Employees Pension System was submitted to the normal session of the Diet, which contained a proposal to relax regulations on early withdrawal from the personal type of defined contribution pension, to improve the Defined Contribution Pension Law.

e. The MHLW, taking into due consideration progress in the enforcement of the various systems and regulations put in place so far, will continue its efforts to improve the defined contribution pension system.

4. Harmonize the Regulatory Framework for Investment Advisory Services and Investment Trusts: The Financial Instruments and Exchange Law has integrated the regulatory structure for these two businesses. In addition, projects among the Investment Advisors and Investment Management industry associations have also provided for harmonization of some aspects of the regulatory structure for these two businesses. In order to enhance consistency in the regulatory environment at the Self-Regulatory Organization (SRO) level, the Government of Japan will provide necessary assistance to the better coordination between Investment Advisors and Investment Management industry associations.

5. Merger and Termination of Investment Trusts: A measure to enable investment trust managers to merge investment trusts was included in the "Amendment Bill of Relevant Laws with Enforcement of the Trust Law," which was passed by the Diet in December 2006. Implementing regulations were drafted and made available for public comment in April 2007. The FSA is currently drafting amendments of the relevant Cabinet Orders and Cabinet Office Ordinances.

   The termination of investment trusts, including advance redemption, is allowed under the existing law, "Investment Trust and Investment Corporations Law", on condition that the procedure for the petition of objection from beneficiary is well established, which is created considering the material impacts on the beneficiary.

6. Institutional Investor Disclosure Rules for Large Shareholdings: The Large Shareholdings Disclosure Rules for Institutional Investors were reviewed in 2006 and the new rules went into effect in January 2007. The FSA will continue to monitor market practices regarding large-shareholding transactions and will make the best efforts to ensure appropriate disclosure of Large Shareholdings under the new Rules, while taking into account adverse impacts on the market.

C. **Transparency**

1. No-Action Letters and General Inquiries Regarding the Interpretation of Laws and Regulations: Following the changes made to the no-action letter system by the FSA in October 2005, five no-action letters have been processed with an average response time of 20 days. Since it was introduced in April 2005, there have been no inquiries under the program for General Inquiries Regarding Interpretation of Laws and Regulations. The FSA is making efforts to consult with the financial industry about how to enhance the utilization of the no-action letter system. The FSA will continue its efforts to improve the effectiveness of the no-action letter system, including through continued dialogue with foreign interested parties.

2. Ensuring Transparency and Effectiveness of the Regulations of the Financial Instruments and Exchange Law: The FSA released the regulations under the Financial Instruments and Exchange Law for public comment in April 2007. The FSA is making efforts to inform the financial industry about the regulations through speaking engagements and official and unofficial contacts with industry associations and domestic and foreign interested parties.

It is urged by the Government of the United States that the FSA continuously endeavor to have opportunities for meaningful dialogues with interested parties, in order to ensure the appropriateness and effectiveness of the regulations, as well as to modify regulations (and laws) as needed over time to improve their effectiveness and to adapt to innovations and other changes in the financial marketplace.

3. Transparency in the Inspections Process: In July 2005, the FSA from the viewpoint of improving the transparency of the inspection process formulated and released officially the Financial Inspection Basic Policy, which sets forth the basic approach and procedures for conducting inspections. And in order to assist in proper inspections, the FSA introduced the inspection monitoring system, by which FSA could provide opportunities for feed back from the financial institutions regarding the implementation of the inspections and more generally, the inspection process.

Moreover, Inspection Manuals, which are guidebooks for inspectors, were wholly revised for insurance companies in June 2006 and deposit-taking institutions in February 2007, while an Inspection Manual for Trust Banks was newly published in July 2006. These manuals were completed through discussions in Working Group comprised of members from various sectors including financial institutions. They are, after soliciting public comments, now open to public, securing the process with high level of transparency. Prior to these steps, Financial Institutions Rating System (FIRST) was also founded in July 2005.

V. COMPETITION POLICY

A. Enhancing the Effectiveness of the Antimonopoly Act (AMA)

1. Strengthening Deterrence of AMA Violations: In order to strengthen the deterrent effect of the AMA:

   a. Based on "The Fair Trade Commission's Policy on Criminal Accusation and Compulsory Investigation of Criminal Cases Regarding Antimonopoly Violations" published in October 2005 in light of the introduction of criminal investigation powers, the Japan Fair Trade Commission (JFTC) will actively bring cases and file criminal accusations against companies and individuals engaging in vicious and serious violations.

   b. In this regard, in FY2006, JFTC filed criminal accusations in two cases including a case involving bid-rigging on a subway construction

project procured by the City of Nagoya. In that case, JFTC filed criminal accusations against five companies and five individuals in February and March 2007.

c. In FY2006, JFTC brought administrative actions against six bid-rigging cases and three price-fixing cartels, and it ordered a record 36.3 billion yen in surcharge payment order against 165 companies.

d. With regard to the continuation of the current system providing both criminal penalties and administrative measures against cartel activities by enterprises, the AMA Study Group is studying this issue. In October 2006, JFTC Chairman Takeshima expressed JFTC's view that the current system should be maintained.

JFTC will examine the system for deterring violation against the AMA, taking into consideration the report concluded by the AMA Basic Issues Study Group in summer 2007 and the discussion at the Study Group. In examining the next steps it will take in responding to the AMA Study Group report, JFTC will take into account any views conveyed to JFTC on this issue or other issues addressed by the AMA Study Group report.

e. For education of public prosecutors, they are given lectures by professionals from JFTC on the method of investigation and disposition of cases involving AMA violations in the specialized training curriculum.

2. <u>Promoting Active Applications to the Leniency Program</u>:

a. JFTC received more than 100 leniency applications from January 4, 2006 until April 30, 2007. JFTC will continuously maximize the effectiveness of the leniency program and promote active applications to the program.

b. In this regard, JFTC published the names and related matters of successful leniency applicants on the bid-rigging cases concerning the following projects:

(1) tunnel ventilation constructions procured by the Metropolitan Expressway Public Corporation (JFTC issued surcharge payment orders in September 2006);

(2) floodgate projects procured by the Ministry of Land, Infrastructure and Transport (MLIT), the Japan Water Agency, and the Ministry of Agriculture, Forestry and Fisheries (JFTC issued cease and desist orders and surcharge payment orders in March, 2007); and

(3) a subway construction project procured by the City of Nagoya.

3. Promoting Transparency of AMA Enforcement and Compliance:

a. On March 28, 2007, JFTC published the revision of the "Guidelines to Application of the Antimonopoly Act Concerning Review of Business Combination" after soliciting and considering public comments. The revised guidelines enhance transparency and predictability of merger reviews by reforming safe harbor thresholds and refining the framework of the reviews concerning pressure from imports, etc.

b. JFTC has published for public comment its proposed new "Guidelines for the Use of Intellectual Property under the Antimonopoly Act," revising the 1999 "Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act." JFTC will finalize the contents of the Guidelines in summer 2007, reflecting opinions provided through the public comment procedure.

4. Reviewing AMA Exemptions:

a. In accordance with the trend towards reviewing the antimonopoly exemption for international aviation in the US, EU and other countries, JFTC has started examination of competition policy issues in the international aviation market, including the AMA exemption, in the "Study Group on Regulations and Competition Policy." The Study Group is expected to issue its report by the end of 2007.

b. Furthermore, since January 2005, JFTC has examined the status of competition in the international shipping market, including the AMA exemption, and in December 2006, it published JFTC's position that the rationale for the AMA exemption is no longer valid. JFTC's report also noted that because the AMA exemption in the international shipping market is provided by the Maritime Transportation Law, whether the AMA exemption is necessary or not should be studied and decided by MLIT in addition to the views of JFTC on this matter.

Taking the published views of JFTC into consideration, MLIT is, as the ministry in charge, going to conduct a necessary study on the AMA exemption in the field of international shipping.

5. Strengthening the Staff Capabilities and Resources of JFTC: JFTC has steadily increased its staff and budget. The total number of its staff is expected to reach 765 as of March 31, 2008, an increase of 28 staff compared to March 2007. JFTC will continue to improve the investigative and economic analytical capabilities of its staff through training and accumulation of practical experience, and will strengthen its organization as appropriate.

B. **Ensuring the Fairness of JFTC Investigatory and Administrative Procedures**

1. Issuance of Decision to Stay Enforcement of Cease and Desist Orders: Section 54 of the AMA provides that JFTC may suspend execution of all or part of a cease and desist order during the hearing procedure if it deems necessary.

When deciding whether it is necessary to suspend execution of the order or not, JFTC needs to take into consideration, on a case by case basis, the necessity of prompt execution of the order, whether the suspension would adversely affect restoration of competition, whether the execution of the order gives rise to a situation in which it is extremely difficult or impossible for the respondent to restore itself to the position in which it would have been, and so on, in a comprehensive manner.

2. Improving Public Confidence in Hearing Procedure: JFTC actively employs lawyers and other outside legal professionals as hearing examiners. As of April 1, 2007, four out of seven hearing examiners are legal professionals. As a result, the panel of hearing examiners for each public hearing will include such legal professionals.

3. Stock Acquisitions: When the parties, in accordance with the "Policies Dealing with Prior Consultation regarding Business Combination Plan, seek a prior and informal consultation with JFTC regarding a concrete plan to acquire stocks of another corporation, JFTC will conduct necessary reviews on the plan and will respond whether JFTC has any intention to take enforcement actions against the stock acquisition under the AMA.

4. Prior Procedures for Measures Based on the Subcontract Act: JFTC publishes recommendations issued under the Act against Delay in Payment of Subcontract Proceed, etc. Prior to issuance of a public measure, JFTC will continue to provide the proposed recipient with the opportunity to present opinions and to submit evidence.

5. AMA Basic Issues Study Group: The AMA Basic Issue Study Group publicized "Points at Issue Concerning the System for Deterring Undertakings from Engaging in Violations against the Antimonopoly Act" and solicited public comments from domestic and foreign interested parties in July 2006. The Study Group also conducted a series of hearings from learned or interested persons and organizations including foreign business organizations such as the American Chamber of Commerce in Japan.

   The Study Group will take into account any comments offered, proceed with discussion and compile the report by summer 2007.

C. **Addressing Bid Rigging**

1. Preventing Conflicts of Interest (*Amakudari*) and Bid Rigging:

   a. The Cabinet approved a bill to amend the National Public Service Act and relevant laws on April 24, 2007, and submitted it to the Diet on April 25, 2007. The bill includes provisions:

      (1) Ensuring personnel management based on competence and achievement; and

(2) Restricting reemployment of retiring government officials, including seeking jobs and brokering employment opportunities.

b. In addition, the Cabinet approved a bill to amend the Local Public Service Law and submitted it to the Diet on May 29, 2007. The bill aims at ensuring personnel management based on competence and achievement, and ensuring appropriate reemployment management of retiring officials.

c. In order to secure public trust in public works projects, as part of MLIT's countermeasures to prevent the recurrence of bid rigging:

(1) Since October 2005, MLIT has requested private firms that have received orders for public works from MLIT not to place former MLIT officials who resigned from MLIT within the last five years in the sales sections of such firms; and

(2) If any of such former officials are employed in such sales sections after October 2005, MLIT has required since December 2006 that all potential bidders report information on such personnel.

d. In January 2007, MLIT established the "Bid Rigging Prevention Measures Study Committee" chaired by the Vice-Minister of Land, Infrastructure and Transport with the participation of non-governmental experts to investigate the facts regarding bid rigging and to study measures for preventing bid rigging. In March 2007, the committee formulated bid rigging prevention measures, which include:

(1) Ensuring thorough compliance with relevant rules;

(2) Expanding the coverage of the open and competitive bidding procedure (e.g. in fiscal year 2008, this procedure will be applied to almost 90% of all contracts by value compared to about 35% in fiscal year 2005);

(3) Strengthening penalties for improper activities, including bid rigging, by extending the period of suspension from bidding and construction business operation; and

(4) Extending the self-enforced rules of reemployment announced in July 2005 to cover reemployment with the companies that were found to have participated in the bid rigging on the flood-gate construction projects or found in the future to have engaged in similar bid rigging on any MLIT public works projects.

2. Expanding Administrative Leniency: In February 2006, MLIT implemented an administrative leniency policy under which MLIT will reduce by half the

period of suspension from bidding for a company that was admitted to JFTC's leniency program with regard to a particular bid rigging conspiracy, provided that MLIT becomes aware of such company's participation in JFTC's leniency program through disclosure by JFTC. In addition, on May 23, 2006, "The Guiding Principles Concerning Measures to Promote Proper Tendering and Contracting for Public Works" were revised by the Cabinet decision to provide that a procuring entity shall endeavor to take into consideration the application of JFTC's leniency program when suspending a company from bidding because of the AMA violation. Based on the Cabinet decision, each central government agency, public corporation, and local government entity covered by the Cabinet decision is expected to implement an administrative leniency program. Recognizing this point, the Government of Japan will conduct a survey regarding the implementation of the Cabinet decision and publish the results within FY2007.

3. Improving Procurement Practices:

   a. The Ministry of Internal Affairs and Communications (MIC), and MLIT will support efforts by the local governments to improve procurement practices.

   b. At the end of March 2007, MIC and MLIT requested the local governments to take measures such as expansion of a general open bidding system, installation of an electronic bidding system, and promotion of publication of bid contract-related information, to promote further the proper tendering and contracting for public works. In addition, MIC is considering banning persons who performed an illegal act from taking part in competitive bidding for up to three years.

VI. COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

A. **Promoting Efficient Restructuring and Shareholder Value through Modern Merger Techniques**: On May 1, 2007, the provisions of the Corporate Code relating to "flexibility of merger consideration" came into effect. As a consequence, foreign companies are now permitted to acquire all of the shares of Japanese companies through a triangular merger, in which the shares of the foreign company are used as consideration for the shares of the target company (i.e., the disappearing company) by a Japanese subsidiary (i.e., the surviving company) of the foreign company.

1. Pursuant to the Ordinance issued by the Ministry of Justice (MOJ), the pre-merger disclosure requirements were expanded for mergers using consideration other than the shares of the surviving company, such as shares of foreign companies; the target company in these mergers will now be required to disclose certain basic, more detailed information to its shareholders prior to the shareholder vote for approval of the merger. The Government of Japan solicited public comments regarding the proposed amendment to the MOJ Ordinance from March 13 to April 11, 2007, and the amendment came into effect on May 1, 2007.

2. Pursuant to the MOJ Ordinance, where the shares of a foreign company that are not transfer restricted are used as merger consideration, the merger must be approved by the special resolution of the shareholders, which requires an affirmative vote of two-third of the votes held by the shareholders present at the shareholders' meeting, just as for domestic mergers.

3. The Government of Japan amended the Tax Code on March 23, 2007, to permit tax deferral on capital gains from the transfer of corporate assets for cross-border triangular mergers, just like mergers between domestic companies, in accordance with the principle of non-discriminatory treatment. According to the Tax Code, the recognition of any gain by the target company or its shareholders as a result of a triangular merger transaction will be deferred for Japanese tax purposes where (1) the surviving company is actually engaged in business operations immediately prior to the transaction and (2) the surviving and target companies meet the "business relationship" requirement. Particular factors that will be considered in making these determinations are set out in more detail in the Ordinance issued by the Ministry of Finance on April 13, 2007.

4. The Government of Japan will monitor the impact of the tax deferral rules on the ability of all investors to take advantage of the triangular merger technique, with a view to revising, if necessary, the conditions for deferral of taxable gain.

B. Strengthening Good Corporate Governance

1. Facilitating and Encouraging Active Proxy Voting:

   a. The Government of Japan recognizes the importance of enhancing corporate governance of listed companies.

   b. The Financial Services Agency (FSA) supports efforts by the stock exchanges to facilitate active proxy voting. The Tokyo Stock Exchange (TSE) has been making efforts to encourage its listed companies to improve the environment for promoting the exercise of voting rights through the provision of proxy materials to shareholders three or four weeks in advance of shareholders meetings and other means. The Government of Japan will engage in dialogues with stock exchanges as to what further actions may appropriately be taken, including possible regulatory changes, to enable shareholders to obtain proxy materials at an early-enough time to permit effective exercise of their voting rights.

   c. From the standpoint of improving the environment in which both domestic and foreign investors would be able to exercise their voting rights adequately, the TSE established a public company to operate the Electronic Voting Platform for Foreign and Institutional Investors. The company launched the services at first for the corporations whose fiscal year ended in December 2005, and more than 200 listed companies are already participating in this platform. The TSE will

continue to invite the listed companies to join the Electronic Voting Platform.

d. The Government of Japan supports the promotion of proxy voting by mutual fund and investment trust managers as a mechanism for increasing corporate value. FSA had been encouraging the Investment Trust Association of Japan (ITAJ) to disclose the summary results of its members' actual proxy voting records. Then, last year the ITAJ conducted a survey on the exercise of proxy voting and announced the results. The public announcement will be implemented this year and beyond continuously.

e. The Ministry of Health, Labor and Welfare (MHLW) has the view that the Employees' Pension Insurance Law and the Defined Benefit Corporate Pension Law impose a fiduciary duty on managers of pension funds and that the fiduciary duty includes an obligation to exercise proxy voting rights solely in the interest of beneficiaries. MHLW will look for opportunities to clarify its view on the fiduciary duty of pension fund managers, including by reviewing its 1997 and 2002 guidelines on the roles and duties of pension fund managers under those laws.

2. Protecting Shareholder Interests:

a. The amended Tender Offer System, which came into effect on December 13, 2006, requires the board of directors of a company that has received a tender offer bid (TOB) to publish a "position statement report" disclosing its position on the TOB. In addition, the target company must state in the report its policy regarding possible introduction or activation of the anti-takeover measures in the amended Tender Offer System.

The law also requires the board to disclose measures the company has taken to avoid potential conflicts of interests on directors in the report. The Government of Japan expects that potential conflicts of interests of boards of directors will be eliminated through compliance with the Securities and Exchange Law requirements regarding responses to TOBs and adoption of anti-takeover measures, and will monitor the effectiveness of the new system in achieving that objective.

b. The TSE announced in its "Development of Comprehensive Improvement Program for Listing System," which was revised in April 2007, that it intends to establish a "Code of Conduct on Corporate Activity" as a TSE rule. TSE expects to issue the first code of conduct by the end of 2007. In addition, TSE through the Advisory Group, intends to consider adopting codes of conduct addressing the need for outside directors and ensuring the independence of outside directors by narrowing the definition of who qualifies as an "outside director."

c. FSA recognizes the importance of enhancing corporate governance of listed companies and will engage in dialogues, as necessary, with stock exchanges regarding their roles in realizing that goal and their efforts for developing their framework and system such as securing the independence of outside board members.

Each of the stock exchanges such as TSE, OSE, JASDAQ have all adopted rules that require listed companies, including those listed on MOTHERS, HERCULES, etc., to promptly disclose details of any anti-takeover measures, and have adopted listing and delisting rules that restrict the ability of listed companies to adopt anti-takeover measures that seriously harm the interests of shareholders.

3. Strengthening the Executive Committee System: The Corporate Code empowers boards of directors of listed companies that have adopted the committee system to delegate certain decision-making powers appropriately to the audit committee. For example, the Corporate Code requires that an accounting auditor (*kaikeikansanin*) be appointed by the resolution of the shareholders' meeting, but empowers the audit committee of a corporation that adopts the committee system to propose the appointment of an accounting auditor to the shareholders' meeting. Moreover, the audit committee of such a corporation has veto power when the directors decide the amount of the compensation for the accounting auditor.

C. **Protecting Foreign Firms Legitimately Doing Business in Japan**: The Government of Japan will continue to watch closely the effects on foreign companies of Article 821 of the Corporate Code and positively consider amendment of Article 821 if necessary to prevent adverse effects on the legitimate operation of foreign companies in Japan.

D. **Permitting Professional Corporations and Branching**

1. The MOJ understands the concerns raised by the Government of the United States that the current legal professional corporation system, which permits Japanese lawyers (*bengoshi*) but not registered foreign lawyers (*gaiben*) to form professional corporations, has effects that disadvantage *gaiben* operating in Japan. Upon receipt of a request from representatives of *gaiben* for the establishment of a professional corporation system for *gaiben*, MOJ will consult with the Japan Federation of Bar Associations (*Nichibenren*) with a view to taking the steps towards amendment of the relevant laws that would permit *gaiben* to form professional corporations on the same basis and with the same benefits as *bengoshi* professional corporations.

2. MOJ will continue to study whether Japanese lawyers, foreign law firms and the *gaiben* partners in Japan should be allowed to establish multiple offices in Japan staffed in accordance with Japanese law without forming a separate Japanese legal professional corporation, from the standpoint of trends in international legal services, including by holding further hearings with *Nichibenren* and *gaiben* on this issue.

E. **Allowing *Bengoshi* to Associate Freely with International Legal Partnerships outside Japan**: MOJ is seriously examining the legal implications, if any, of *bengoshi* becoming members of international legal partnerships. To that end, MOJ will diligently research on the practice of international legal partnerships in FY2007.

F. **Promoting Arbitration and Other Alternative Dispute Resolution (ADR)**

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; 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; and 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.

2. 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.

3. The Act on Promotion of Use of Alternative Dispute Resolution (ADR Act), which allows for the promotion of ADR in a manner that is consistent with international norms and practices, will be implemented in a manner that contributes to the goal of establishing Japan as a center for international dispute resolution.

   The Government of Japan utilized the Public Comment Procedure before establishing MOJ ordinances and guidelines on implementation of the ADR Act. The Government of Japan will ensure that the Public Comment Procedure will continued to be used when establishing and revising laws, ordinances and guidelines related to the implementation of the ADR Act.

4. The Government of Japan was informed that the Japan Association of Arbitrators had solicited opinions from related parties in establishing the ethics code for arbitrators.

VII. TRANSPARENCY

A. **Transparency Practices**: The Government of Japan recognizes the importance of an open and transparent business climate as a necessary condition for greater trade and investment opportunities. High transparency standards contribute to economic growth by helping ensure accountability, stability and trust in the fairness and effectiveness of governance. The Government of Japan also notes the view of the Government of the United States that consistency and predictability in the manner by which Ministries and Agencies ensure transparency is necessary. The Government of Japan will further continue to work to achieve high-standard transparency practices and will discuss and exchange information with the Government of the United States on

transparency best practices in the Cross Sectoral Working Group under the U.S.-Japan Regulatory Reform and Competition Policy Initiative.

1. Public Input into Policy Development – Advisory Groups: 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.

   a. Lists of all advisory groups and their membership as well as related information are electronically accessible through "e-Gov," a government portal website (http://www.e-gov.go.jp).

   b. The Government of Japan will continue to promote measures in accordance with an April 1999 Cabinet Decision titled “Basic Plan for the Rationalization of Councils, etc” and other guidelines regarding transparency of and access to advisory groups.

2. Public Comment Procedure: 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.

   a. Requirements stipulated in the APA include the following: 1) Ministries and Agencies set comment periods of at least 30 days in principle to provide meaningful opportunities for input from the public; and 2) Ministries and Agencies fully take comments into consideration before their draft orders/regulations are made final.

   b. For a meaningful implementation of the PCP, the Government of Japan regards it also important to further familiarize the public with the procedure, including its implementation, and to address questions and concerns from the public. Additionally, the Ministry of Internal Affairs and Communications (MIC) will continue to conduct and publish a comprehensive annual survey on the Ministries’ and Agencies’ implementation of the PCP, and will maintain close communications with relevant Ministries and Agencies, encouraging and promoting better implementation of the procedure as necessary.

3. Transparency in Regulation and Regulatory Enforcement: The Government of Japan understands the importance of the private sector having sufficient information on regulations and ensuring interpretations and commentaries of laws and regulations are easily available to the public by providing information and various standards on application of laws. The Government of Japan notes the view of the United States regarding the need for introduction of clear requirements of Ministries and Agencies to make generally-applicable interpretations of regulations available to the public.

4. Public Input into the Development of Legislation: Some Ministries and Agencies, at their discretion, have been opting for public input into draft

legislation during its development, utilizing the public comment procedure and other measures, before it is submitted to the Diet.

5. Foreign Translations of Japanese Laws: On March 23, 2007, the Government of Japan, with due consideration to opinions of domestic and foreign experts, revised the Translation Development Program for FY2006-FY2008. The revision increases by 50 the number of English translations of Japanese laws and regulations to be translated, which will now total approximately 250 translations under the program. Based on the program, the Government of Japan has produced approximately 80 English translations of laws and regulations as of the end of April 2007. The translations are available on the Cabinet Secretariat's Website (http://www.cas.go.jp/jp/seisaku/hourei/data1.html). The Government of Japan will continue to ensure timely translations of laws of greatest relevance to interested parties.

6. Implementation of Rulemaking: The Government of Japan will further ensure reasonable periods between the publication of final regulations and their effective date by providing the effective dates of the regulations well in advance of implementation so that interested parties can prepare for the change.

7. Special Zones for Structural Reform: The Government of Japan will continue to:

   a. Take the necessary steps to ensure that successful zones have the largest economic impact on the greater Japanese economy;

   b. Apply successful regulatory exemptions in the Special Zones on a national basis as expeditiously as possible (the Government of Japan has applied a total of 71 zone measures nationwide as of March 31, 2007) and operate the entire application and regulatory exemption process for the Special Zones in a transparent manner;

   c. Consult with local governments and foreign companies to implement zones;

   d. Publish information on the ideas accepted and measures taken; and

   e. Provide information in English to the greatest extent possible.

B. **International Cooperation**: Japan and the United States will continue their joint efforts to encourage Asia-Pacific Economic Cooperation (APEC) member economies to fully implement the APEC Transparency Standards in their domestic legal regimes and to use APEC transparency model measures as a reference for future trade agreements. The Government of Japan will also intensify cooperation with the Government of the United States through other means to promote high-standard transparency practices in the Asia-Pacific region that help improve business and investment environments throughout the region**.**

VIII. OTHER TRADE-RELATED GOVERNMENT PRACTICES

A. Bank Sales of Insurance

1. The Ministerial Ordinance of the Insurance Business Law was partly amended on July 8, 2005, based on the report of the Second Sub-Committee of the Financial Council, issued on March 31, 2004.

2. This amendment partly lifted the ban on selling insurance products at bank branches on December 22, 2005, and introduced consumer protection safeguards with respect to sales of insurance through banks. After monitoring the effectiveness of these safeguards until December 2007, the Financial Services Agency (FSA) plans to lift the ban on selling any insurance product at banks and will implement related technical preparations prior to full liberalization.

3. 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.

4. Taking medium and small size financial institutions' business into consideration, the FSA has relaxed the limitation of the customer of insurance solicitation by banks and has carried the preferential measures to relax the restriction separating the person in charge of business loan from one in charge of insurance soliciting business. The restriction as to the insurance amount (10 million yen ceiling on both life insurance and third sector insurance products) provided by medium and small size financial institutions was intended to limit damage of the insurance contractors. The Government of the United States welcomes the commitment of the Government of Japan to review, and if necessary revise, the 10 million yen ceiling on third sector insurance products prior to full liberalization in December 2007.

   In the process of reviewing the regulation on selling insurance by banks, FSA took into consideration opinions of various interested parties, including domestic and foreign insurance companies and banks, associations of insurance agents, associations of medium and small size companies and representatives of consumer, and solicited public comments on the draft amendments of the Cabinet and Ministerial Ordinances of Insurance Business Law. During the process of monitoring insurance solicitation by banks, the FSA will hold regular hearings with insurance companies (including foreign companies), banks, and other various interested parties as necessary.

B. Insurance Cooperatives (*Kyosai*)

1. With regard to unregulated *kyosai*, an amendment to the Insurance Business Law, which came into effect on April 1, 2006, expanded its scope to include unregulated *kyosai* and introduced the Small Amount and Short-Term Insurance Providers (SASTIP) system.

2. During the process of the consideration of this reform, the Financial Services Agency (FSA) consulted with the Financial System Council, exchanged opinions with foreign insurance companies, and published a draft amendment of the relevant ministerial ordinance for public comments.

3. The Amended Insurance Business Law stipulates that FSA will review the SASTIP system within five years from the date of its enforcement. 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.

4. With regard to *kyosai*, the Government of Japan recognizes the request by the Government of the United States that the Government of Japan ensure the establishment of a level playing field between kyosai and their private sector competitors by subjecting *kyosai* to the same laws, requirements, standards, and oversight by the same regulator as their Financial Services Agency (FSA)-regulated competitors and that a review be undertaken in the near-term to evaluate the consistency of regulation and supervision among *kyosai* that are regulated by ministries other than the FSA, to determine their conformity with FSA standards of supervision for private insurance service suppliers and such a review should be undertaken in a transparent manner with meaningful opportunities for interested parties to express and exchange views.

C. Policyholder Protection Corporation

1. The amended Insurance Business Law, which came into effect on April 1, 2006, extended the period of existence of the scheme of the Insurance Policyholder Protection Corporation (PPC), including government-funded resources as financial assistance in case of an insurance company bankruptcy. This amended law also stipulates that the system regarding PPC's financial resources will be reviewed within three years after April 1, 2006.

2. In implementing this review, the Financial Services Agency and related advisory groups convened by the Government of Japan will provide, upon request, private sector interested parties (including foreign insurance companies) information on the review as well as meaningful opportunities to express and exchange views.

D. Government Practices Relating to Agriculture

1. Plant Quarantine:

   a. *Cosmopolitan Pests Review*: The Government of Japan added one of the four quarantine pests concerning lettuce, identified by the Government of the United States, to the list of non-quarantine pests. The Government of Japan will continue its pest risk analyses (PRAs) to determine the quarantine status of the remaining three pests of priority interest to the Government of the United States, as part of Japan's overall Cosmopolitan pest review process, based on international standards.

b. *Joint Risk Assessment*: The Government of Japan shares with the Government of the United States the understanding that it is meaningful to have dialogue between respective PRA experts, and notes that the two governments are appreciative of the past collaborative work conducted on the pest risk assessment for Japanese Persimmon and look forward to continued work together on addressing issues related to pest risk assessments, as appropriate.

2. Maximum Residue Limits Enforcement Policy: The Government of Japan recognizes that when it confirms that regulation and management systems for agricultural chemicals and veterinary drugs in an exporting country are equivalent to those in Japan, it is possible to impose strengthened inspection exclusively on the specific violator concerned, i.e., manufacturer, producer, etc., in the exporting country, consistent with measures taken domestically in Japan in the event of an agricultural chemical residue violation. Exchanges of information and technical discussions are underway between the Governments of Japan and the United States in order to advance this process.

3. Animal Products: The Government of Japan is working with the Government of the United States towards science-based solutions for these issues.

4. Agricultural Biotechnology:

a. *IP Handling*: The Government of Japan confirmed that the following procedures are necessary to remove labeling requirements for agricultural products from an exporting country in which genetically modified varieties of those agricultural products were once planted for commercial purpose but are no longer planted for such purpose:

(1) The Government of the exporting country concerned presents an official document establishing that commercial planting of genetically modified agricultural products is no longer conducted in its country;

(2) The Government of Japan will report to the relevant advisory board; and

(3) The Government of Japan revises "Questions and Answers on Food Labeling (the third part: labeling of genetically modified foods)."

The Government of Japan was provided relevant data and information by the Government of the United States demonstrating that genetically engineered potatoes currently are not commercially grown in the United States. The Government of Japan will report to the meeting of the advisory board on food labeling in the summer of 2007 and the Government of the United States is supplying information in support of this. The Government of Japan has been working with the Government of the United States using the process described above to

make an appropriate determination regarding labeling requirements for U.S. potatoes and products thereof.

b. *Feed Approval System*:

(1) The Government of Japan has taken steps to consider the needs of applicants regarding the approval system for biotech feed, and recently the Subcommittee on GM Feed was held around five times per year.

(2) The Government of Japan has published the approval procedures in ministerial announcements and the Ministry of Agriculture, Forestry and Fisheries (MAFF) accepts applications from companies at any time.

(3) The Government of Japan and the Government of the United States share the understanding that the presence of non-approved feed could cause serious problems in the trade of feed. In order to avoid occurrence of such trade problems, both governments will exchange information and cooperate with each other to improve the efficiency and predictability in implementation of the approval system for biotech feed.

5. Safety Evaluation of Food Additives:

a. With regard to the 46 food additives and flavorings, which are proven safe internationally (e.g. by the FAO/WHO Joint Expert Committee on Food Additives (JECFA)) and are widely used, the Government of Japan, without the submission of a dossier from industry, is proceeding with the considerations on the authorization of these additives and flavorings. The Ministry of Health, Labour and Welfare (MHLW), following the results of evaluation by the Food Safety Commission, has approved the use of 7 of these food additives and 12 flavorings since 2003.

b. Regarding polysorbates for which requests for acceleration of the review process were received from the U.S. and others, the Government of Japan is making progress in the necessary procedures for their authorization, specifically on the Food Safety Commission's evaluation. The MHLW is taking steps to allow for final designation by establishing standards. Regarding the review of remaining substances, the MHLW will continue to work with the Food Safety Commission.

c. In order that evaluations on the health effects of food undertaken at the Food Safety Commission and discussions on specifications and standards carried out by the Pharmaceutical Affairs and Food Sanitation Council are advanced both promptly and smoothly, the Government of Japan seeks the cooperation of its trading partners by requesting specific data as needed.

IX. PRIVATIZATION – JAPAN POST

A. Level Playing Field for Postal Savings and 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") will be disclosed under the same regulations as other private sector companies, including those under the Corporate Code, Banking Law, Insurance Business Law, other related laws and ordinances, and, when engaging in public capital market transactions, the Financial Instruments and Exchange Law (Securities and Exchange Law). From the beginning of the privatization transition period, the Financial Services Agency (FSA) will have sole authority over the supervision and inspection of Japan Post Bank and Japan Post Insurance under the Banking Law and Insurance Business Law, and will apply 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 shall be implemented to ensure that the privatized postal financial institutions, in practice, objectively meet the same licensing, disclosure, and supervisory requirements as private sector financial institutions, including requisite risk management and full FSA supervision. Therefore, the FSA will set up a new office with a director and 11 more staff in its Supervisory Bureau. Furthermore, Japan Post Network, including its employees, will be subject to FSA supervision when acting as an agent or intermediary to order any financial transactions such as taking deposits, lending, exchange transaction and selling insurance products. The relationships and transactions among Japan Post Bank, Japan Post Insurance, Japan Post Holdings, and Japan Post Network will be 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 laws on postal services privatization are designed to prevent ex-post cross-subsidization among the newly established 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 Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance will be established 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 will not be covered by the Deposit Insurance or Policyholder Protection scheme in case of the bankruptcy of Japan Post Bank or Japan Post Insurance. Japan Post will prepare and disclose its financial statements as of September 30, 2007, after being audited by an independent

auditor. The Valuation Committee will value assets and liabilities succeeded to the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance, and this valuation will be, in principle, on fair value basis. The Government of Japan shares the view with the Government of the United States that the timely and meaningful public disclosure of this valuation is important. 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 audited by an independent auditor in accordance with Japanese GAAP. The laws stipulate that, from October 2007, the asset management arisen from inherited pre-privatized accounts and contracts will be 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 shall be subject to the Banking Law and Insurance Business Law as well as to FSA inspection and supervision and will be on a commercial basis. The deposit and reinsurance contracts will be stipulated in the implementation plan. The implementation plan will be reviewed by the Prime Minister and the Minister of Internal Affairs and Communications in the process of approval. When these two ministers approve the implementation plan, they will be required to hear opinion from the Postal Services Privatization Committee (PSPC) and consult with the Minister of Finance. The Process will ensure that profit arising from pre-privatized accounts and contracts are not unfairly transferred to Japan Post Bank and Japan Post Insurance through the deposit and reinsurance contracts.

3. The existing laws governing the privatization of Japan Post allow Japan Post Network to make insurance soliciting contracts with private insurance companies other than Japan Post Insurance and to make agency contracts with private banks other than Japan Post Bank. In terms of access to Japan Post Network's network, equivalent conditions of competition is 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 will ensure 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.

4. Beginning October 1, 2007, deposits received by Japan Post Bank and the life insurance products sold by Japan Post Insurance will not be guaranteed by the Government. The PSPC states the following views: the perception of an "implicit government guarantee" is based on a misunderstanding of depositors and policyholders, etc.; Japan Post Bank and Japan Post Insurance should explain the nonexistence of government guarantee; and the government should make utmost efforts to eliminate such misunderstanding. The Government of Japan will follow the view of the PSPC appropriately and take measures as necessary. Sales of such products after privatization that are misrepresented as being guaranteed by the Government are prohibited by the Banking Law and Insurance Business Law.

5. The Antimonopoly Act will continue to be applied to Japan Post; furthermore, it will be applied to the new postal companies on the same basis and according to the same standards as it is applied to any other private companies. In this regard, the Japan Fair Trade Commission (JFTC) is carefully monitoring the practices of Japan Post, and will do so regarding the newly established postal companies. JFTC, as appropriate, will continue to express its views on competition policy issues concerning the operation of the newly-privatized Japan Post companies as well as the privatization of Japan Post.

6. 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 undue 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 company is also obliged to publish a report on how the Activity was implemented within 3 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 shall be subject to the laws and regulations applied to private financial institutions such as the Banking Law and Insurance Business Law. In addition, the laws on postal services privatization impose business restrictions on both postal financial institutions during the transitional period. The initial scope of business of Japan Post Bank and Japan Post Insurance will be the same as that of Japan Post. Future 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, will 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 will be 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 will be ensured as mentioned above by the Government of Japan throughout the postal privatization process, including when the ministers in charge make decisions on the business expansions 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 same “duty declaration” system will be applied to customs clearance procedures for international physical distribution services provided by Japan Post or Japan Post Service as those applied to those for other private companies. The Government of Japan reviewed its customs clearance system for international postal items and will, in principle, apply the "duty declaration" system to international postal items that are valued at over 200,000 yen. The Government of Japan is aware of the Government of the United States’ view that customs clearance regulations and procedures for EMS and similar international express delivery services provided by Japan Post should be applied in the same manner to similar shipments provided by private express carriers.

2. Japan Post should disclose the status of profit and loss according to the categories of postal services and international physical distribution services. Also, Japan Post Service should disclose the status of profit and loss according to the categories of postal services and other services. These disclosures, a measure taken by the Government of Japan, are to be made in a manner that will allow for an objective evaluation of whether cross-subsidization is occurring. The Government of Japan is aware of the Government of the United States’ view that all necessary public disclosure measures should be taken to ensure that cross-subsidization between EMS (and similar international express delivery services) and other products provided by Japan Post Service does not occur.

D. **Transparency**

1. 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 PSPC has made the opportunities to hear views of interested parties regarding postal services privatization issues. The chairman 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.

   The Office for the Promotion of Privatization of Postal Services, Ministry of Internal Affairs and Communications, and FSA will continue to provide opportunities for private sector interested parties, upon request, to exchange views with relevant officials. While recognizing the independence of the PSPC, the Government of Japan also recognizes the importance of the transparency of the PSPC.

2. 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. Japan Post Holdings submitted the implementation plan to the Prime Minister and Minister of Internal Affairs and Communications for approval on April 27, 2007.

The Government of Japan will ensure that the implementation plan, including the deposit and reinsurance contracts, will be made available upon request in accordance with the Act on Access to Information Held by Administrative Organs. The Government of Japan recognizes that stakeholders can have meaningful opportunities to review such documents through the above-mentioned procedure and that stakeholders can express views in a timely manner. The Government of Japan is aware of the expectation of the Government of the United States that material portions of the plan should be made available in a timely manner before final decisions are made.

3. Under the Standing Order of the PSPC, the PSPC is to in principle make 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 publicly available prior to the meeting, has held the post-meeting press briefing, and has made the summary and the detailed meeting minutes publicly available. The Secretariat of PSPC will continue to make advance notice of the PSPC's agenda publicly available (including on the relevant website) prior to each PSPC meeting.

4. 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

1. Airport fees are determined through discussion between the airport companies and the airlines. With regard to the Narita International Airport, the landing charges were reduced in 2005, and were accepted by the IATA. An advisory panel of well-informed independent personalities was set up to discuss the future of international airports in Japan in October 2006. The panel produced its report in March 2007. Among other things, the panel's report discusses appropriate elements to consider when pricing airport services such as the need for at least minimal regulation. The report is available on the web site of the Ministry of Land, Infrastructure and Transport (MLIT).

2. In line with the declaration of ICAO Council, the airport landing charge in Japan is basically imposed to cover the cost of using airport facilities by aircraft operators, in case of airports administrated by national authority, taking the weight and noise-value of aircraft as the basis for its calculation. Besides, it is explained to IATA before its final decision is compiled into the Aeronautical Information Publication (AIP).

B. **Airport Expansion and Operation**: Narita International Airport Corporation (NAA), which was privatized in April 2004, has a strong incentive for profits. NAA's profit for the year ending March 2007 was 10.3 billion yen. NAA has carried out its B runway expansion in an effective and cost-conscious way. This project will increase the capacity of the airport and enhance utilization by larger aircrafts with the B runway. For this reason, this project is supported by airlines and other countries, which have strong demands for more service to Narita, and will increase NAA's profit.

C. **Customs Processing**

1. Separate Customs Treatment for Express Consignments: The Customs and Tariff Bureau (CTB) of the Ministry of Finance has implemented several measures which will streamline or expedite the customs clearance process including establishing the Preliminary Examination System, the Instant Import Permit Upon Arrival System and has given its permission for importers and exporters to declare goods via manifest. In addition, CTB has endeavored to facilitate customs clearance through such measures as stationing customs officers on a 24/7 basis at the customs clearance divisions of major airports.

2. Customs Declarations:

   a. In 2001 CTB introduced the Simplified Procedure which separated the declaration process for cargo release from the duty payment process for authorized importers found to have a high degree of compliance with customs regulations. The Government of Japan takes note of the view of the Government of the United States that the coverage of this system should be expanded to include customs brokers.

   b. The Government of Japan takes note of the view of the Government of the United States that users of the Nippon Automated Cargo Clearance 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.

D. **Customs *de Minimis***: The Government of Japan takes note of the view of the Government of the United States that the current *de minimis* rate should be raised.

E. **Parking Spaces for Distribution Vehicles**:

1. The new Road Traffic Law and related enforcement guidelines, which took effect in June 2006, have been successful in reducing traffic jams, accidents and illegal parking.

2. Each Prefectural Police department has been enforcing the parking regulations developed based on consultations with local residents and carriers, paying attention not only to safety and smoothness in traffic and the need for parking but also to the usefulness of parking for carriers engaging in cargo delivery.

In the meantime, the National Police Agency recognizes the request for mitigation measures by industry, including U.S. industry.

3. One of the principal intentions of the Road Traffic Law is to reduce the number of "unattended vehicles." Parking enforcers have been instructed to observe whether the driver is inside or in the vicinity of an unattended vehicle before affixing a ticket, and to give only a warning when the driver comes back to the car before affixing a ticket. Parking within 5 minutes for the purpose of loading and unloading of cargo is legally permitted as long as the driver is inside or in the vicinity of the vehicle.

4. The National Police Agency (NPA) recognizes the importance of distribution and has given local authorities discretion to exclude distribution vehicles from the regulations as appropriate. NPA will continue to consider improving enforcement of parking regulations and parking permit procedures including with regard to distribution vehicles, taking into account requests from industry including U.S industry. In addition, NPA will reaffirm to local authorities the importance of lenience when enforcing parking rules with respect to distribution vehicles.

5. The Government of Japan will continue to endeavor to improve urban facility and traffic management by:

   a. Encouraging road authorities to maintain existing and develop additional loading and unloading zones; and

   b. Recommending that local governments establish ordinances to provide parking facilities, including for commercial vehicles, in newly constructed or newly renovated buildings of a certain usage and size.

F. **Speed Implementation of the Revised Road Transport Vehicles Law (RTVL)**: In May 2006, the Diet amended the Revised Road Transport Vehicles Law to establish a new Automobile Owner Identification System which would come into effect within two and one-half years, by November 2008. In June 2006, the Government of Japan convened an advisory board consisting of interested parties and government representatives to determine concrete measures to be taken in order to introduce the Automobile Owner Identification System.

G. **Laws Affecting Large Scale Retail Stores**:

1. Before the amended City Planning Law comes into effect completely on November 30, 2007, the Government of Japan has established the amended law's implementing guidelines in a transparent and fair manner. The Government of Japan explained to the Government of the United States that local governments are expected to implement the law in a transparent and fair manner through the city-planning procedures which include opportunities for the private sector as well as other interested parties to express their views in accordance with the law's implementing guidelines.

2. The Government of Japan will review the impact of the City Planning Law in a timely manner after it comes into effect, including assuring that the law is not implemented in a way that would restore the commercial adjustment system or restrict the business model of large-scale retail stores as such, and in a manner that includes opportunities for the private sector as well as other interested parties to express their views. The Government of the United States made a request on the timing to review the impact of the law. The Government of Japan expressed its views on this matter.

3. The Government of Japan has explained the purpose and the system of the Central City Invigoration Law.

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.

C. With respect to the issue of 'zeroing' in WTO/DS322, the Government of the United States notes that this issue is being considered as part of U.S. implementation under dispute settlement procedures.

D. The Government of the United States will continue to work closely with Congress on legislation to implement the WTO recommendations and rulings in the Hot-Rolled Steel 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.

E. Section 801 of the U.S. Revenue Act of 1916 (Anti-dumping Act of 1916) was repealed on December 3, 2004. The Government of the United States is aware of the Government of Japan's concerns with respect to the Anti-Dumping Act of 1916.

F. The Government of the United States has explained its views with respect to the Government of Japan's concerns on certain other U.S. anti-dumping issues.

II. INVESTMENT-RELATED REGULATIONS

A. Exon-Florio Amendment

1. The Government of the United States recognizes the Government of Japan's concerns on the "Exon-Florio" provision regarding, inter alia, predictability of regulations, legal stability of completed transactions, and ensuring due process. In implementing Exon-Florio, the Government of the United States is mindful of the Government of Japan's concerns.

2. The Government of the United States takes note of the concerns raised by the Government of Japan with regard to legislation introduced in Congress to reform the CFIUS review process, and its concern that new legislation could lead to hindering foreign investment in the United States. The Government of the United States recognizes the economic benefits of foreign investment and is committed to maintaining an open economic system that welcomes foreign investment.

III. DISTRIBUTION AND CUSTOMS PROCEDURES

A. **Maritime Transport Security**: The Government of the United States shares with the Government of Japan an understanding of the importance of balancing security considerations with the need to facilitate international trade. The security and efficiency of the international supply chain and the maritime transportation system that supports it are critical to global prosperity. From this point of view, the Government of the United States notes Japan's request regarding this issue and is committed to balancing its initiatives for counter-terrorism with rapid, smooth and effective distribution. The Government of the United States is also committed to working with the international community to develop common procedures and standards that will complement modern business practices while improving public safety. The Government of the United States appreciates the efforts of Japan to support capacity building to implement the World Customs Organization's *Framework of Standards to Secure and Facilitate Global Trade*, and the support it has received for the Container Security Initiative (CSI). The U.S.-Japan Study Group established under the U.S.-Japan Sub-Cabinet Economic Dialogue will actively address ways in which the United States and Japan can cooperate to secure and facilitate global trade.

1. Advance Electronic Presentation of Cargo Information: Advance information and strategic intelligence allow the identification of cargo shipments that pose a potential risk to safety and security before the cargo is loaded on vessels. This risk management approach to cargo processing is becoming a recognized international best practice. The advancement of modern business information systems increasingly creates opportunities for risk analysis earlier in the supply chain, providing multiple opportunities to resolve potential threats. The Government of the United States worked closely with the trade community in developing the regulations to implement the advance electronic information requirements of the Trade Act. The requirements were gradually implemented recognizing the adjustment necessary in business processes. These requirements mandate a reasonable timeframe to allow the analysis of the information so that only safe cargo will enter the maritime transportation system. Advance electronic information also enhances risk analysis efforts by using the cargo data to identify and facilitate shipments by known compliant entities. In turn, advance information allows for improved focus on non-compliant and unknown trade entities. The Government of the United States notes Japan's concern that, as the private sector adapts to the new requirements, this approach can affect efforts by importers to shorten lead times within their supply chains. Taking note of the request of the Government of Japan with regard to deregulation of the advance presentation of electric cargo information, the Government of the United States will continue to work to enhance the compatibility of security measures and efficient distribution, and continue working with the international community through organizations such as the International Maritime Organization and the World Customs Organization to achieve greater international uniformity in requirements for the international transportation of cargo.

2. C-TPAT: The Customs-Trade Partnership Against Terrorism (C-TPAT) is a voluntary government-business initiative to build cooperative relationships that strengthen and improve international supply chain security. The Government of the United States screens 100% of cargo using advance electronic commercial information and law enforcement information systems. Although the participants enjoyed the benefits of moderated analysis of the threat and reduced probability of inspection, C-TPAT has been elaborated with the introduction of the tiered benefit system to provide expanded benefits to the members who have enhanced their security measures. The Government of the United States fully understands Japan's request that more tangible benefits should be given to C-TPAT participants. The Government of the United States will take appropriate measures to expand tangible benefits to C-TPAT participants and will continue to facilitate private sector engagement in an effort to enhance the transparency in the process of implementation and further revision of C-TPAT rules.

B. **The Bioterrorism Act and Related Regulations**

1. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) (PL 107-188), authorized the U.S. Food and Drug Administration (FDA) to develop regulations to implement four provisions in the Act, including section 307 (Prior Notice of Imported Food Shipments). FDA and U.S. Customs and Border Protection jointly issued the Prior Notice Interim Final Rule in October 2003, which allowed affected parties an additional opportunity to comment on the interim final rule's provisions while the rule took effect on December 12, 2003, as required by the Bioterrorism Act. FDA and CBP issued a Compliance Policy Guide in December 2003 (most recently revised in November 2005) regarding the exercise of enforcement discretion. FDA is carefully considering all comments it received during an open comment period on the Prior Notice Interim Final Rule, including those filed by the Government of Japan, and the areas addressed by the Compliance Policy Guide, as it develops the final rule, with the objective of developing provisions that are consistent with the Bioterrorism Act and its legislative history, and that achieve the Act's objectives, while minimizing the impact on trade to the extent feasible.

2. The United States notes that FDA's "Compliance Policy Guide" initially published in December 2003 (and most recently revised in November 2005) provides that "FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper" and such article is not typically refused by FDA and CBP even without prior notice, regardless of whether the food is sent by international mail or home-delivery services (see http://www.cfsan.fda.gov/~pn/cpgpn6.html).

3. FDA's goal is to publish the final rule for Prior Notice as soon as possible. The draft final rule is currently undergoing internal U.S. review.

4. The United States Embassy in Tokyo recognizes and appreciates the high level of interest in compliance with the Bioterrorism Act by Japanese food

processors, postal and other delivery service providers, and the general public in Japan. The Embassy will provide relevant links on its website to both English and Japanese language sites regarding any significant developments under the Bioterrorism Act that may have an impact on food processors and senders in Japan, and provide assistance to the public in Japanese, including advice over the telephone on what they need to do to comply with the Act. The Embassy welcomes further discussion with the Government of Japan and interested parties on how to improve outreach regarding the Act efficiently and effectively.

C. **Merchandise Processing Fee (MPF)**: The United States' Merchandise Processing Fee is limited in amount to the approximate costs of services rendered. The Government of the United States takes note of the request by the Government of Japan that the MPF not exceed the approximate costs of services rendered.

D. **Regulations on Alcoholic Beverages**

1. Regulations on the Standard of Fill for Bottled Distilled Spirits: The Government of the United States notes the concern of the Government of Japan regarding the standards of fill for distilled spirits products sold in the United States and notes the Government of Japan's request to amend this regulation. The Government of the United States provided information to the Government of Japan on the procedures and rules based on Title 27 Code of Federal Regulations (CFR) § 70.701(c) that would allow anyone to file a petition to have the regulations concerning standards of fill modified. The Government of Japan, if it desires, can start the process by initiating the procedures outlined by of 27 CFR Part 70.

2. Certificates of Label Approval on Alcohol Beverages Imported into the United States: The Government of the United States notes the concern of the Government of Japan concerning the importation of alcohol beverage samples for trade shows and for soliciting sales as trade samples. The current regulations in Title 27 CFR §27.49 and §27.74 only allow very limited quantities of samples to be imported without a certificate of label approval (COLA). The Government of the United States issued the March 29, 2007, Alcohol and Tobacco Tax and Trade Bureau (TTB) notice "Importing Samples for Trade Shows and/or Soliciting Orders" that under certain conditions allows samples of alcohol beverages to be imported, by licensed importers, without a COLA for the purpose of trade shows or to be used as trade samples. While TTB has no set upper limit as to quantities, it is noted that the agency evaluates the requests on a case-by-case basis and must be satisfied that the quantities could reasonably correspond to use as sales samples. This notice is not an amendment but only clarification of long-standing practice.

3. On-Sale Licenses for Alcohol Beverages: The Government of the United States notes the concern of the Government of Japan regarding the retail sales of Japanese shochu in the state of California and of New York. Under the Federal Alcohol Administration Act, retail sales of alcohol beverages mainly fall under the jurisdiction of State law.

a. The Government of the United States has informed the Government of Japan that it has the option of petitioning the States of California and New York for an exemption or to request an amendment of their respective State laws to allow for the sale of Japanese shochu for consumption under a beer and wine license or to be sold at retail under a beer and wine license.

b. The Government of the United States has contacted the State of California to bring the Government of Japan's recommendation to the attention of the relevant State agency, which has conveyed that California State law has a limited exception for distilled spirits labeled as "soju" that is no more than 24 percent alcohol by volume and is imported into the United States (Section 23398.5 of the California Business and Professions Code). The State of California has further noted that "shochu" would qualify under this exception if the label on the product also identifies it as "soju" and is no more than 24 percent alcohol by volume.

c. Although retail sales of alcohol beverages mainly fall under the jurisdiction of State law, the Government of the United States will forward the concerns of the Government of Japan to the States of California and New York with regard to permitting the sale of shochu with the on-sale license for beers and wines as applied to the sales of soju.

IV. CONSULAR AFFAIRS

A. Visa Process

1. Efficiency in Visa Revalidation Procedures: The Government of the United States is actively exploring ways to facilitate visa processing, using technology where possible to improve security while making it easier for legitimate travelers to obtain visas and renew them, as noted in the Rice-Chertoff Initiative announced in January 2006.

   a. Visa revalidation in the United States was halted in July 2004, among other reasons, due to the requirements to issue biometric visas and interview applicants. The Visa Office has no means for domestic collection of biometrics from visa applicants and does not interview domestically. The Government of the United States understands the concerns raised by the Government of Japan about the impact of this decision on visa holders. The United States Government continues to study options to address these concerns.

   b. The Department of State is exploring ways to expedite E visa applications, including through an online visa application being piloted this summer, and make it possible for more posts to accept renewal applications from third country nationals. The Government of the

United States and the Government of Japan will continue to engage in regular dialogue on visa issues.

2. Introduction of Visa Services into the Other Consulates in Japan: The Government of the United States responded to the request by the Government of Japan to expand visa services in Japan by starting monthly non-immigrant visa processing at the United States Consulate General in Sapporo in April 2006. Sapporo has processed 878 non-immigrant visa cases since April 2006 and schedules 25 appointments per day, two appointment days per month, to meet the demand. The Government of the United States began limited visa services at the U.S. Consulate in Fukuoka on May 9, 2007.

3. Visa Issuance and Terms of Validity:

a. The Government of the United States notes the concern raised by the Government of Japan regarding L visa reciprocity. L visas cannot exceed the validity of the petition approved by USCIS. USCIS regulations state that petitions can only be valid for three years.

b. The Government of the United States acknowledges the request by the Government of Japan concerning E-visa qualification requirements.

c. The Government of the United States has made great strides in shortening times for application-related appointments and processing. Currently, most Japanese who require a visa and qualify for a visa receive their visa within one week of beginning the visa application process.

B. **Driver's Licenses**

1. Real ID Act:

a. The Department of Homeland Security (DHS) is in the process of developing regulations that will establish the minimum standards for State governments to follow when issuing driver's licenses or other forms of State-issued identification, pursuant to the Real ID Act, signed into law by President Bush on May 11, 2005, and scheduled to take effect in 2008.

b. All States have entered into a Memorandum of Understanding (MOU) with DHS to verify the legal presence of all non-citizen driver's license applicants using the Systematic Alien Verification for Entitlements (SAVE) to verify a driver's license applicant's lawful status. For all non-citizens authorized to be in the United States for a temporary period, the Real ID Act states that the validity period of a driver's license or identification card issued by the State may not exceed the period of authorized stay.

c. How States will implement the new law's provisions remains unclear at this point. The Act accords the Secretary of Homeland Security, in

consultation with the Secretary of Transportation and the States, the authority to issue regulations, certify compliance, and issue grants pursuant to the Act. DHS published a Notice of Proposed Rule-Making in the Federal Register on March 8, 2007. The proposed rule was open for public comment through May 8, 2007. The Government of Japan submitted comments on the proposed rule of the Real ID Act to the Government of the United States on May 8, 2007. The Government of the United States understands the concerns raised by the Government of Japan and will consider in the rule-making process the comments submitted by the Government of Japan and others. DHS will continue to seek input from stakeholders as regulations are developed, and acknowledges the request of the Government of Japan that, in the course of the implementation of the Act, States should also consider the issues currently affecting Japanese and other foreign nationals as a result of States' driver's license regulations.

d. The Government of the United States is sensitive to the concerns raised by the Government of Japan about the length of driver's license validity periods. However, the Government of the United States must interpret the meaning of the terms in the Real ID Act in a manner consistent with the language of the Act and the intent of Congress.

2. Improvement of State Rules:

a. The Government of the United States recognizes that the Government of Japan is concerned about some State regulations regarding driver's licenses, including international driver's permits, State of Georgia confiscation laws, State of Massachusetts sponsor requirements, and State of Tennessee driver's certificates.

b. The Georgia and Massachusetts practices apply to all persons, and are not special rules directed at non-citizens. The Government of the Unites States notes the Government of Japan's concerns about the disposition of surrendered licenses and has approached the State of Georgia to convey the concerns. The State of Georgia confirmed that licenses are confiscated and destroyed as required by Georgia code (Section 40-5-1). Because laws governing driver's licenses are determined by the States, the federal government has a very limited ability to affect State statutes.

c. It is possible in Tennessee to obtain a "Tennessee ID," which is a different document from a driver's certificate and can be obtained by any Tennessee resident who has proper documentation from DHS proving legal residency.

C. **Immigration Control**

1. U.S. Customs and Border Protection (CBP) has developed US PASS as an alternative CBP inspection system for pre-screened, approved, air travelers entering the United States. US PASS will be the principal program used by

the United States for processing all low-risk international air travelers, replacing the discontinued INSPASS program.

2. CBP plans to implement US PASS on a pilot basis in 2007. It will be available for participants entering the United States at the John F. Kennedy (JFK) International Airport, Houston Intercontinental Airport, and Washington Dulles International Airport. US PASS may be expanded to additional locations after evaluation of the pilot.

3. US PASS will facilitate travel by allowing enrollees to present their machine-readable travel document, submit their fingerprints for biometric verification, and make a declaration at an automated kiosk. Upon successful completion of this process, a traveler may move to baggage claim and exit unless chosen for a selective or random secondary inspection.

4. Participation in the US PASS pilot program is voluntary. The pilot program will initially be open to U.S. citizens and U.S. Lawful Permanent Residents. CBP developed US PASS to incorporate US-VISIT. Future members of US PASS who are required to undergo US-VISIT processing at the time of their arrival will do this at the US PASS kiosk, which will be identical to the US-VISIT Departure kiosk.

5. Membership in the program will be granted after successful completion of a CBP background investigation based on biographical information provided by the applicant through an on-line application, followed by a personal interview and the collection of biometric data.

6. CBP has implemented enhancements to SENTRI to improve the application/enrollment process. The length of validity of program membership has been extended from two years to five years. Applications are now submitted electronically by the applicants through a secure web-site. All background vetting of applicants is done at a single centralized vetting center instead of at individual enrollment centers. CBP has reduced the backlog of applications to be processed and membership renewals from 18 months to 1 month. CBP continues to work on expanding the number of dedicated lanes available at Ports of Entry for the use of SENTRI members.

D. Handling of Emergency and Travel Documents for Return to Japan without Biometric Identifiers

1. U.S. Customs and Border Protection (CBP) informed the Government of Japan in September 2005 of the conditions under which CBP would grant a parole to nationals of Visa Waiver Program (VWP) countries with non-machine-readable emergency or temporary passports. Such VWP travelers must meet the following conditions: 1) must have had a passport lost, stolen or expired while outside the home country; 2) must present an emergency or temporary passport or other emergency travel document issued by a government authority to replace a lost or stolen passport; 3) must be in direct and continuous transit through the United States for the purpose of returning home; 4) must have confirmed airline tickets (or electronic ticket record) for

return to the home country; 5) must be otherwise admissible to the United States; and 6) will be required to pay the $65 parole fee if granted a parole.

2. A VWP country emergency, temporary, official and/or diplomatic passport that is machine readable is valid for VWP travel. This includes the Japanese temporary travel document. In addition, a VWP country emergency, temporary, official and/or diplomatic passport is not subject to the digital photo or electronic chip requirement. VWP nationals presenting emergency or temporary passports that are not machine-readable may be granted a parole, with fee. Emergency passports do not need to comply with the biometric requirement.

E. **Permission to Stay**

1. Expeditious Extension of Permission to Stay:

a. The Government of the United States understands the concern of the Government of Japan on the need for timely extensions of permission to stay.

b. Japanese nationals are extended the same benefits by statute as all foreign nationals. The current processing time for extensions of stay is approximately 60 days. There is a premium option that guarantees fifteen calendar day processing. This option requires an additional fee of $1,000.

2. Extension and Automatic Renewal of Validity of Permission to Stay:

a. The Government of the United States notes the request of the Government of Japan to extend the term of validity of the Permission to Stay (I-94).

b. U.S. Citizenship and Immigration Services (USCIS) has prioritized backlog elimination since FY2006, and has made significant strides towards accomplishing its backlog elimination goals.

c. USCIS has set the agency's priorities as 1) ensuring national security, 2) reducing the backlog, and 3) improving customer service. 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.

d. 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.

F. **Social Security Number (SSN)**

1. Expeditious Issuance of Social Security Number:

   a. In order to improve social security number processing times, in January 2007 all Social Security Administration field offices began using a more efficient system of verifying immigration documents called the electronic additional verification (EAV) process. The EAV process has replaced the time-consuming, paper-based G-845 verification process and has already reduced processing time for issuing social security numbers to non-U.S. citizens. The G-845 process is now only used when DHS is unable to verify documents via the EAV process. DHS now sends out EAV responses within 15 business days, a great improvement over the paper-based system.

   b. In collaboration with the Department of State, the Social Security Administration (SSA) has taken steps to improve the Enumeration at Entry (EAE) process by expanding it to include certain non-immigrant visa categories, and SSA will review this process with a view to possible expansion.

2. Issuance of Social Security Numbers to Dependents of Employment Visa Holders: The Government of the United States fully understands the concerns of the Government of Japan regarding the assignment of social security numbers for dependents of employment visa holders. The Government of the United States recognizes an individual as eligible for a social security number if they have DHS work authorization or if they have a valid non-work reason for a social security number. The SSA website (http://www.ssa.gov/pubs/10120.html) provides information on rules for getting a social security number and card as well as a link to Questions about SSNs for Non-Citizens.

G. **Individual Taxpayer Identification Number**: The Internal Revenue Service (IRS) notes the concern raised by the Government of Japan with regard to the Individual Taxpayer Identification Number (ITIN), and appreciates that an undue delay in the issuance of an ITIN can create an inconvenience. The U.S. Government encourages individuals who may seek an ITIN to explore fully the exceptions under which an ITIN will be issued without satisfying the requirement of attaching an individual income tax return, noting that if the criteria for any one of the four exceptions are met, the ITIN can be issued at any time during the year. A full explanation can be found in IRS Publication 1915 – Guide to Understanding ITIN. This publication, along with Form W-7, can be found on the IRS web site (www.irs.gov), keyword ITIN.

V. 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 United States acknowledges that its first-to-invent system is unique. While the first-to-file system is used in most countries, it remains controversial in the United States. Legislation to adopt the first-to-file approach is currently pending in the U.S. Congress (H.R.1908 and S.1145). The United States will continue to pursue and participate in discussions with Japan and other World Intellectual Property Organization (WIPO) Group B member countries on patent law harmonization, which includes discussion of draft provisions written from a first-to-file perspective.

B. **Early Publication System**: The United States is evaluating the application of exceptions to the early publication system. This issue is also addressed in the above-referenced legislation (H.R.1908 and S.1145).

C. **Reexamination System**: Changes to the U.S. reexamination system continue to be widely discussed, including new provisions to implement post-grant opposition proceedings, which are also addressed in proposed legislation (H.R.1908 and S.1145).

D. **Unity of Invention**: The Government of the United States recognizes that its standard of decision for unity of invention is more stringent than that of the Patent Cooperation Treaty and is currently studying the adoption of eased requirements for a unity of invention standard.

E. **Hilmer Doctrine and Article 102(e) of the Patent Act**: The Government of the United States acknowledges that the Government of Japan has concerns regarding the Hilmer Doctrine and Article 102 (e) of the Patent Act. The Government of the United States notes that these issues are being discussed in the ongoing substantive patent law harmonization talks between the United States, Japan, and other WIPO Group B members. The United States will continue to participate in these discussions. These issues are also addressed in proposed legislation (H.R.1908 and S.1145).

F. **Information Disclosure Requirement of Prior Art**: The Government of the United States recognizes the Government of Japan's concern with respect to the information disclosure requirement of Prior Art, especially the proposed rule change of the IDS requirement announced in July 2006. As to the Government of Japan's concerns regarding translations, the Government of the United States notes that English translations are only required to be submitted if the translation is readily available. As to the Government of Japan's request to shorten the period of the information disclosure requirement, in the current view of the Government of the United States, applicants must timely disclose information that is known to be material to patentability at all times during patent prosecution and before the issuance of a patent. The Government of the United States notes the views of the Government of Japan and will evaluate the appropriateness of its measures with a view to ensuring that they do not impose undue burden on patent applicants.

G. **Plant Patent**: The Government of the United States notes the concern expressed by the Government of Japan regarding the difference in the novelty requirements in the patent laws and in Article 6 of the International Convention for the Protection of New Varieties of Plants (UPOV Convention). The Government of the United States would like to discuss with the Government of Japan what, in their view, are the important

aspects of the novelty test according to the UPOV Convention, and how to address the issue raised by the Government of Japan.

VI. GOVERNMENT PROCUREMENT

A. The Government of the United States waives the application of the Buy American Act (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. The Government of the United States takes note of the Government of Japan's concerns with Buy American restrictions.

B. The Department of Defense (DoD) opposes the imposition of new domestic restrictions by the Congress. The U.S. Annex 1 to Appendix I of the GPA sets out the exclusions for the Department of Defense, as well as a list of the covered items. In addition, the covered items are listed in the Federal Defense Acquisition Regulations Supplement (DFARS) 225.4-70 (http://www.acq.osd.mil/dpap/dfars/html/current/225_4.htm). With respect to the BAA, defense products of countries with which the Department has established Reciprocal Defense Procurement Memorandum of Understanding (RDP MOU) are considered as domestic since both parties to these agreements have agreed to remove barriers to their defense procurements to the same extent for each others' industries. DoD officials who handle the Buy American Act, the Berry Amendment, and the Specialty Metals restriction have offered to serve as primary contacts for any questions.

C. The 2005 Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (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 the Buy American restrictions attached to the Federal funds for those projects and thus the restrictions continue to apply. The Government of the United States explained that the Federal Transit Administration was considering all comments it received during an open comment period on the proposed rulemaking of its Buy American requirement based on the SAFETEA-LU as it develops the final rule, including those filed by the Government of Japan.

VII. STANDARDS AND CRITERIA

A. Weight Limit for Containers

1. The Government of the United States notes the concerns of the Government of Japan that the Interstate weight limits set by the federal law could affect transport costs.

2. As previously discussed between Department of Transportation's Federal Highway Administration (FHWA) and representatives of the Government of

Japan, U.S. States have the option to consider, as "non-divisible loads," cargoes that are carried in containers moving in international commerce (i.e., either originating in another country or destined thereto). Various, but not all, States have chosen to exercise this option. Thus, if State policy allows containers moving in international commerce to be issued permits as non-divisible loads, a State can issue an overweight permit allowing the loads on the Interstate. As each State is responsible for operating and maintaining their highway transportation infrastructure and has the most complete knowledge of what routes can support or accommodate overweight movements, they are currently and, according to constitutional powers reserved to the state, should continue to be the permitting authority for overweight movements. The FHWA has been, and will continue to, work with the states to develop regional permits that could facilitate commercial moves between the ports and the end destination.

3. FHWA notes that ISO standards are voluntary by their nature and not mandated upon any government to use. The Government of the United States has a legal responsibility to work with the States to enforce the truck size and weight statutes and the rules and regulations that have been promulgated through a rigorous process. The Government of the United States recognizes the importance of the international harmonization of container weight limits.

4. The Government of the United States and the Government of Japan will continue to exchange views and information on this issue. FHWA's Commercial Vehicle Size and Weight Team is willing to continue to work with the Government of Japan on the federal weight limits, and to discuss any additional concerns. The Government of the United States has a map available of the National Highway System on the internet, which reflects the major routes of travel through the United States (http://hepgis.fhwa.dot.gov/hepgis_v2/Highway/Map.aspx). The Government of the United States takes note of the Government of Japan's idea that a mapping tool be made available on a government website that would facilitate highway selection for container movement from the starting point to the end destination.

B. **Promotion of the Metric System**

1. The U.S. National Institute of Standards and Technology (NIST) continues to promote the use of the metric system (SI) throughout the economy; work to remove barriers to the voluntary metric system use; and increase public metric system understanding through educational information, guidance, and in Government publications.

2. Regarding labeling, over 90 percent of U.S. states now permit the use of metric-only units on packages that are subject to their exclusive jurisdiction, including automotive accessories, clothing, and household furnishings. NIST is working with three remaining states to encourage these jurisdictions to amend their laws and regulations to permit voluntary metric-only labeling. With respect to measures at the Federal Government level, NIST continues to undertake efforts to develop industry and public support for an update to the

Fair Packaging and Labeling Act (FPLA) that would permit metric-only labeling. A NIST working group updated a report titled *Permissible Metric-Only Labeling* in late 2005 that sought to increase awareness on this issue.

3. Regarding new technologies, NIST recently assisted the National Aeronautics and Space Administration (NASA) in studies of its metric use policies. NASA announced in early 2007 that it will use metric measurements for all operations to and on the lunar surface when it returns to the moon with its international partners. This decision will result in increased metric system use among NASA engineers and technical staff, contractors and the U.S. aerospace industry. NIST has also consulted with both internal and industry nanotechnology experts and found consensus supporting the exclusive use of metric units in this emerging field. NIST will continue to recommend that the equivalent SI units are stated when a non-SI unit is used in a scientific publication to facilitate data interpretation.

4. NIST welcomes and encourages the Government of Japan's provision of priority examples that illustrate where increased metric system use would facilitate trade and commerce.

C. Harmonization of Environmental Regulations on Industrial Products

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

2. Through the Resource Conservation and Recovery Act (RCRA), Congress mandated EPA to establish federal-level regulations regarding the management of solid and hazardous wastes. EPA, in turn, can authorize the states to implement their own solid and hazardous waste programs, provided that these programs meet the minimum federal-level requirements under RCRA. States may establish more stringent regulations for solid and hazardous waste management, based on their individual needs, but may not establish less rigorous regulations than those enacted by EPA.

3. In order to assist the regulated community in understanding minimum federal requirements under RCRA and any additional state-level regulations related to waste management, EPA provides a variety of information resources, including on-line and print documents, access to the full text of regulations, and training courses. EPA's web site on Wastes (http://www.epa.gov/epaoswer/osw/stateweb.htm), for instance, provides access to each state's information on solid and hazardous waste management regulations and guidelines. Similarly, EPA's National Environmental Compliance Assistance Clearinghouse (http://cfpub2.epa.gov/clearinghouse/index.cfm) provides access to state-level environmental regulations both on waste management and on other issues, and features other tools that can help the private sector understand and comply with environmental regulations.

4. EPA will continue to make information available to our state and local partners on best practices for environmental management, including information on standards setting, enforcement, and compliance. The EPA will also continue to explore the possibility of improving access to state-level regulations through its web site based on a request by the Government of Japan to create a single portal web page to facilitate comparisons of state-level environmental regulations.

D. **Feed and Surveillance Measures**: The Government of the United States is working with the Government of Japan towards science-based solutions for these issues.

VIII. EXTRATERRITORIAL APPLICATION

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. In response to the Government of Japan's recommendations regarding U.S. re-export controls, however, the Bureau of Industry and Security (BIS) has:

    a. Posted re-export guidance, translated into Japanese, on its website in 2003;

    b. Hosted a two-day educational outreach seminar in Tokyo in February 2007, which focused on, *inter alia*, re-export controls; and

    c. Expressed its willingness to facilitate a remedy where possible should the Government of Japan provide specific examples regarding concerns that some of the information on the BIS Japanese website may be difficult to use.

2. While there is no U.S. legal requirement for U.S. companies to provide Export Control Classification Numbers (ECCN) to their customers, BIS is considering other ways for U.S. exporters to share this information, including:

    a. Having suggested to industry through one of its Technical Advisory Committees (TACs) that the provision of ECCNs is good customer service, and will consider making this suggestion to all six of its TACs; and

    b. Started exploring the possibility of adding a field to its electronic Classification Request form that would ask applicants for permission to publish the ECCN on the Bureau's website.

B. Sanctions Acts

1. Iran Sanctions Act: The Government of the United States takes seriously the concerns of its trading partners. In response to issues raised by the Government of Japan, the United States stated that the Iran Sanctions Act

(ISA, previously known as the Iran and Libya Sanctions Act, or ILSA) reflects the 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 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 dialogue with the Government of Japan.

2. Cuban Liberty and Solidarity Act of 1996:

   a. 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). 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).

   b. Most recently, on January 17, 2007, the President sent a letter to Congress consistent with the Act to suspend for six months beyond February 1, 2007, the right to bring an action under Title III of the Act.

3. Sanctions Acts Instituted by Local Governments: The Government of the United States takes sanctions measures by state and local governments seriously and looks at them closely. The Government of the United States has made considerable efforts over the years to reach out to state and local authorities to help ensure that initiatives at the state or local level support U.S. foreign policy. The Government of the United States will continue those efforts when needed, taking full account of its international obligations and policy concerns.

IX. COMPETITION POLICY (ANTITRUST EXEMPTIONS)

A. On April 2, 2007, the Antitrust Modernization Commission ("AMC") submitted its Report and Recommendations to the Congress and to the President on the results of its three-year comprehensive review of whether federal antitrust law should be modernized. The AMC's conclusions with regard to antitrust exemptions and immunities included the following recommendations:

1. Statutory immunities from the antitrust should be disfavored. They should be granted rarely, and only where, and for long as, a clear case has been made that the conduct in question would subject the actors to antitrust liability *and* is necessary to satisfy a specific societal goal that trumps the benefits of a free market to consumers and the U.S. economy in general;

2. Courts should construe all immunities and exemptions from the antitrust laws narrowly; and

3. Congress should evaluate whether the filed-rate ("Keogh") doctrine should continue to apply in regulated industries and consider whether to overrule it legislatively where the regulatory agency no longer specifically reviews proposed rates. The Keogh doctrine prohibits private plaintiffs from pursuing treble damage antitrust actions based on a claim that a rate submitted to, and approved by, a regulator resulted from an antitrust violation.

   The Administration and the Congress are reviewing the AMC Report and will give careful consideration to all of the recommendations of the AMC, including those related to antitrust exemptions and immunities.

B. The federal antitrust agencies of the United States continue to look for opportunities to express their views on the appropriate scope of exemptions to and immunities from the application of the federal antitrust laws with a view to promoting competition for the benefit of U.S. consumers. In that regard, in November 2006, the Federal Trade Commission (FTC) issued a staff report on its enforcement perspective regarding the proper parameters of the Noerr-Pennington doctrine, which precludes enforcement of the antitrust laws against certain private acts that urge government action. The report recommends that the scope of the Noerr-Pennington doctrine be clarified so that it does not include: 1) petitions of the government, outside of the political arena, that seek no more than a ministerial government act; 2) misrepresentations to a government decision-maker outside of the political arena; and 3) patterns of repetitive petitioning for government action, outside of the political arena, filed without regard to merit that employ government processes, rather than the outcome of those processes, to harm competitors. The report also recommends that the FTC clarify or limit the application of the Noerr-Pennington doctrine, as recommended above, through FTC enforcement actions or *amicus* filings in other cases.

C. On March 30, 2007, the Department of Transportation issued a decision discontinuing its grant of antitrust immunity to discussions or agreements among United States and foreign air carriers on fares, rates, conditions of service, and price and rate applicability conditions, through IATA tariff conferences, for passenger and cargo air services 1) between the United States and the European Union (together with Iceland, Norway, Switzerland, and Liechtenstein); 2) between the United States and the overseas territories of the member states of the European Union subject to an air services agreement between the United States and a member state; and 3) between the United States and Australia (see http://dmses.dot.gov/docimages/pdf100/463755_web.pdf).

D. Postal reform legislation that contains provisions designed to subject certain activities of the U.S. Postal Service to the antitrust laws was enacted in 2006.

X. LEGAL SYSTEM

A. The Government of the United States continues to be committed to ensuring that the business community is not unduly burdened by inappropriate product liability litigation and unreasonable damage awards.

B. In February 2007, the United States Supreme Court issued its opinion in *Philip Morris USA v. Williams*, 127 S.Ct. 1057 (2007), which concerned the Constitutionality of a punitive damage award of $79.5 million by an Oregon state trial court against a cigarette manufacturer for its deceitful practices that led to the death of the plaintiff. The U.S. Supreme Court held that the Constitution's Due Process Clause prohibits the use of punitive damage awards to punish defendants for injury caused to persons not parties to the litigation. This decision has the effect of limiting the basis on which punitive damages may be awarded.

XI. SERVICES

A. Maritime Transportation Business

1. Merchant Marine Act of 1920 and the Reporting Requirement on the Situation of Japanese Ports: 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 reiterated its concerns about Japanese port operations, but will continue to consult and exchange information with the Government of Japan in order to remain informed of the situation of Japanese ports and any positive developments, and will keep the Federal Maritime Commission (FMC) informed of the situation of Japanese ports.

2. Ocean Shipping Reform Act of 1998: The Government of the United States explained that in the past the Government of the United States had stated the language added in 1998 to the Merchant Marine Act did not grant new authority. Rather, it merely clarified the pre-existing authority of the Federal Maritime Commission to address discriminatory and unfair competitive practices of carriers in U.S. trade. As such, the Government of the United States does not plan to change this policy which is mandated by U.S. law.

3. Maritime Security Program: The Government of the United States exchanged views with the Government of Japan and will continue to ensure that the Government of Japan is kept informed of the list of the dedicated vessels and any changes in this important national security measure. Information on the Maritime Security Program is publicly available at the Maritime Administration's website (http://www.marad.dot.gov/programs/index.html).

4. 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 measures such as cargo preferences may distort conditions for free and fair competition in the international maritime market. With respect to these issues, the Government of the United States explained the following: United States Government-owned cargoes covered by cargo preference laws, including the transport of U.S. military cargo, represent less than one percent of the United States' total ocean borne foreign trades; and 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.

B. **Legal Services**

1. In August 2006 the American Bar Association (ABA) amended its Model Rule for the Licensing and Practice of Foreign Legal Consultants (Model Rule). The Model Rule would now require an applicant to have been lawfully engaged in the practice of law and to have been a member in good standing of a recognized legal profession in a foreign country for at least five years, and no longer would require the legal experience to have been obtained within seven years of the application. The Model Rule also drops provisions that would establish a minimum age requirement for applicants or that would allow the licensing body of a State to take into consideration whether the home country of the foreign lawyer provides reciprocal treatment to lawyers of that State.

2. The American Bar Association continues 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 Model Rule.

3. On August 2, 2006, the Conference of Chief Justices, an organization whose membership is composed of the highest judicial officer in each State and territory of the United States, adopted a resolution urging the highest court of each State that has not already done so to consider adopting a rule permitting the licensing and practice of foreign legal consultants.

C. **Harmonization and Unification of the State-based Construction Business Licenses**: Based on the U.S. federal system, the federal government does not have jurisdiction over the issuance of construction licenses for operations within state borders. The Government of the United States noted the progress made by the National Association of State Contractors Licensing Agencies (NASCLA) in developing a national examination program for construction licenses. The program requires test providers to pass an audit of their business/financial and test development and administration procedures before their examinations are accredited by NASCLA. The first examination will be for commercial general contractors and is expected to be available by the end of 2007. NASCLA has developed the infrastructure for the examination, including application procedures, state agency responsibilities, test provider responsibilities, and NASCLA staffing. NASCLA is also developing a database that will help facilitate the use of examination information across states and expedite licensing procedures. The Government of the United States will continue to provide the Government of Japan with relevant information on this issue, as appropriate.

D. **Insurance Business**

1. 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 under its 2003

Regulatory Modernization Action Plan. The following highlights are among the Plan's achievements to date:

a. In addition to the adoption of standardized filing requirements and uniform standards for licensing among all U.S. states, the NAIC continues to implement its Financial Regulation Standards and Accreditation Program (the standards of which are in place in all U.S. jurisdictions) and to continue to refine its model laws and national guidance, including with respect to annuities, reinsurance, long-term care, and health insurance.

b. As of May 2007, 30 state legislatures have adopted the Interstate Insurance Product Regulation Compact, exceeding the threshold necessary for the Compact to take effect. An interstate commission will develop uniform national product standards and a central filing register to strengthen the speed and efficiency of regulatory decisions among member states in the areas of life insurance, annuities, disability, and long-term care insurance. The NAIC will continue to work with the states to encourage greater adoption of the Compact. Legislation to adopt the Compact is pending in 10 state legislatures. Product filings are due to begin June 2007.

c. A total of 51 insurance jurisdictions, including the District of Columbia and Puerto Rico, are utilizing the System for Electronic Rate and Form Filing (SERFF), the electronic based system for enhancing speed and efficiency for insurance provider applications. On average, filings take an average of 23 days. As of the end of 2006, the system had logged approximately 269,101 electronic filings under this system.

2. Following a December 2006 recommendation officially voted on by the NAIC Reinsurance Task Force, the NAIC has undertaken a broad review of reinsurance regulation in the United States. As part of this, the Task Force is developing a proposal to use a company rating process based upon broad based risk and credit criteria as a means for determining collateral requirements that could:

a. Use ratings given by international financial rating companies as for a component of the criteria for determining collateral requirements, which could lead to a system under which unlicensed non-U.S. firms could be required to post less than 100% collateral for its U.S. liabilities.

b. The proposal is due to be completed by September 2007 with implementation to be undertaken as part of the broader reform of U.S. reinsurance regulation. Proposal drafts will be considered in upcoming Task Force meetings and other related meetings, which are open to foreign interested parties. Input will be solicited regularly from a group of interested parties, which includes representatives of Japan's insurance industry.

3. The Government of the United States notes that the Government of Japan welcomes efforts to modernize the insurance regulatory system in the United States. The Government of the United States is aware that the Government of Japan has highlighted its interest in initiatives relating to a federal regulatory system. The introduction of federal insurance regulations has been discussed in both houses of Congress of the United States.

4. The Government of the United States will continue to facilitate communications, as appropriate, between the Government of Japan and the NAIC on issues relating to state-based regulations. The NAIC has also provided a direct point of contact for issues raised by the Government of Japan, which will be directed within the NAIC to appropriate parties.

XII. FINANCIAL SERVICES

A. The Issue of Samurai Bond Accompanied with the Book-entry Transfer System

1. Historically the U.S. tax law has permitted bonds to be considered in bearer form if the holder of the bond is able at some time to obtain a definitive, that is, a certificate representing the holder's ownership of the bond. The effect of bearer classification is that the holder of the bond does not need to provide documentation concerning its foreign status to obtain exemption from U.S. withholding tax.

2. However, under the new Japanese book-entry system, a holder of a bond is not able to obtain a definitive unless the entire book-entry system ceases to exist. In the recent guidance, the U.S. Treasury articulated that this very remote situation is insufficient under the current regulations to permit the bond to be considered as issued in bearer form. Accordingly, the issuance of a Samurai bond through the book-entry system will be considered to be in registered form and will require the holder to provide documentation of its foreign status before being entitled to exemption from U.S. withholding tax. To this claim, the government of Japan requests the government of the United States to apply the rule of Foreign Targeted Registered (FTR) to Samurai bond, because the government of Japan assumes that the claim of the U.S. government may bring serious impact on the sound development of Samurai bond market, though the market has benefits for both U.S. companies and Japanese investors.

3. However, the U.S. Treasury determined that the documentation and tax reporting requirements of the FTR rules were inconsistent with the tax policy behind the development of the qualified intermediary program. The U.S. Treasury stated in the October 2006 guidance that it would issue regulations that permit the continued use of the FTR rules for bonds issued within two years from January 1, 2007, and whose maturities are less than or equal to ten years. The Government of Japan requests that the restriction on applying the FTR rules be relaxed to harmonize with the sound development of the Samurai bond market. Based on such circumstances, while the government of the United States appreciates and shares the concern expressed by the government of Japan for the continued growth and efficiency of the Samurai bond market, the United States must continue to evaluate the impact of the most recent U.S.

guidance, as well as Japan's recommendation, in light of the documentation and tax reporting requirements set forth in the regulations establishing the qualified intermediary regime.

B. **Regulations on Sales and Offers of Foreign Investment Trusts**

1. Although, by its terms, Rule 7d-1 promulgated under the Investment Company Act of 1940 (Company Act) applies only to Canadian investment companies, the Securities and Exchange Commission (SEC) historically has also required non-Canadian foreign investment companies seeking 7(d) orders to comply with the rule's conditions. The SEC staff remains willing to consider applications for 7(d) orders from any foreign investment company, including those organized in Japan.

2. Moreover, additional avenues for access to the U.S. market for asset management services exist. Indeed, SEC staff interpretations and innovations in the mutual fund industry have significantly increased the ability of foreign advisers, which can easily register with the SEC, to offer their services to U.S. investors and to establish funds that are organized in the United States.

C. **Licensing New York Branches of Japanese Banks to Conduct Stock Futures and Commodity Futures Trading on Their Own Account**

1. U.S. banks are generally prohibited, by Federal banking law, from trading or otherwise investing in equity securities (including exchange-traded funds), or futures and other derivatives based on those assets for their own account. Both Federal and New York law similarly prohibit such activities with respect to physical commodities, or futures and other derivatives based on those assets. As an exception to these general prohibitions, U.S. banks may invest in equities or commodities, or futures and other derivatives based on those assets, when those investments are designed to hedge exposures generated by customer-driven transactions, including on a portfolio basis.

2. These same limitations, and the exceptions, are applied equally to U.S. branches and agencies of foreign banks, consistent with the policy of national treatment. The New York State Banking Department lacks the statutory authority to authorize greater powers for New York-licensed offices of foreign banks than are enjoyed by domestic banks. Even if the New York State Banking Department had such authority, it would not be appropriate for the U.S. government to intervene with respect to a state banking department's prudential restrictions applied to financial institutions licensed by that state.

3. Bank holding companies, especially those that have elected financial holding company status, have somewhat greater authority to invest in equities and commodities, as well as futures or other derivatives based on those assets. Again consistent with national treatment, foreign banks may exercise these powers in the United States through nonbanking subsidiaries.

4. Moreover, the New York prohibition does not necessarily create any "disparity" between the practices permitted for foreign banks as opposed to

other managed fund entities. For example, a number of states bar state employee pension plans from trading futures and options products.

XIII. TELECOMMUNICATIONS

A. Participation in the U.S. Wireless Market

1. The Government of the United States will continue to provide information to the Government of Japan on the classification between common carriers and non-common-carriers and the distinction between tariffed and non-tariffed services in the United States.

2. The Federal Communications Commission (FCC) has granted licenses for two foreign-affiliated operators in the U.S. wireless market over the past year: operators controlled by NTT DoCoMo, of Japan, for providing service in Guam; and America Movil of Mexico, for providing service in Puerto Rico. In addition, in April 2007, KDDI America, Inc. entered the U.S. wireless market as a mobile virtual network operator (MVNO) with the brand name KDDI Mobile and has obtained licenses for operating in 49 states.

3. The FCC's first auction of Advanced Wireless Service (AWS) spectrum licenses (1.7 and 2.1 GHz bands) ended on September 18, 2006. A total of 1,122 licenses were offered in the auction, and 104 bidders won 1,087 licenses. The top five winning bidders based on the net amount of their winning bids include: T-Mobile License LLC; Cellco Partnership d/b/a Verizon Wireless; SpectrumCo LLC; MetroPCS AWS, LLC; and Cingular AWS, LLC.

4. During 2005, the number of mobile telephone subscribers in the United States rose from 184.7 million to 213 million, increasing the nationwide penetration rate to approximately 71 percent. The amount of time mobile subscribers spend talking and texting on their mobile phones has also increased and the volume of text message traffic grew to 48.7 billion messages in the second half of 2005, nearly double the 24.7 billion messages in the same period of 2004. Revenue per minute, which generally reflects the retail price of mobile telephone service, fell 22 percent during 2005 from $0.09 in 2004 to $0.07 in 2005.

B. Regulatory Reform in the Broadband Era

1. The FCC declared Broadband over Power Line (BPL)-enabled Internet access service to be an information service in November 2006. The FCC also declared wireless broadband Internet access service to be an information service in March 2007. These actions place BPL-enabled Internet access and wireless broadband Internet access services on an equal regulatory footing with other broadband services, such as cable modem service and DSL Internet access service.

2. On March 12 2007, the FCC initiated a Notice of Inquiry (NOI) to better understand the behavior of participants in the market for broadband services.

The Commission in its 2005 Internet Policy Statement announced four principles to encourage broadband deployment and to preserve and promote the open and interconnected nature of the public Internet. This NOI seeks information on the behavior of broadband market participants, including: how broadband providers are managing Internet traffic on their networks today; whether providers charge different prices for different speeds or capacities of service; whether FCC policies should distinguish between content providers that charge end users for access to content and those that do not; and how consumers are affected by these practices.

C. **Competition in the Navigation Devices Market in the Process of Transition to Digital Television**: 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). Under current rules, U.S. cable operators must make available a security element separate from the set-top box. This requirement is intended to enable unaffiliated manufacturers, retailers, and other vendors to commercially market set-top boxes and other devices while allowing the cable operator to retain control over system security. Beginning on July 1, 2007 (unless granted individual waivers), cable operator must also use separable security in their set-top boxes, thus promoting market-based choice for such devices.

D. **Access Charges**: In July 2006, the Commission issued a Public Notice seeking comment on a comprehensive intercarrier compensation reform plan (the "Missoula Plan") filed by the National Association of Regulatory Utility Commissioners' (NARUC) Task Force on Intercarrier Compensation. Numerous comments were received in response to the Public Notice, the due date for which was extended to February 1, 2007. Additionally, the Commission requested and recently received comment on proposed amendments to the Missoula Plan, including a process for the creation and exchange of call detail records and a new regulatory support mechanism intended to assist states that have already rebalanced rates.

E. **Universal Service**

1. <u>FCC Updates Approach for Assessing Contributions to Universal Service Fund (USF)</u>:

   a. In June 2006, the Commission raised the existing wireless "safe harbor" percentage used to estimate interstate revenue from 28.5 percent to 37.1 percent of total end-user telecommunications revenue to better reflect growing demand for wireless services. This interim wireless safe harbor was last updated in 2002. Wireless carriers continue to retain the option to base contributions on their actual revenues or on traffic studies that estimate their actual interstate revenues.

   b. In June 2006 the Commission also expanded the base of USF contributions by extending universal service contribution obligations to providers of interconnected voice over Internet Protocol (VoIP) service. For interconnected VoIP providers, the Commission

establishes a safe harbor percentage of interstate revenue at 64.9 percent of total VoIP service revenue.

2. Federal-State Universal Service Joint Board Staff Releases Monitoring Report: The staff of the Federal-State Joint Board on Universal Service released its most recent Monitoring Report on Universal Service in December 2006. This report reflects information on the telephone industry filed with the FCC through May 2006. The report addresses the various universal service support mechanisms, which amounted to about $6.5 billion in 2005. In 2005, disbursements among the four categories of universal service mechanisms were: 58.7% for high-cost support; 28.6% for schools and libraries support; 12.4% for low-income support; and 0.4% for rural health care support. The report presents data in eleven categories.

3. The FCC Issues a Proposed Rulemaking to Address Universal Service Disbursements: On May 14, 2007, the FCC issued a Notice of Proposed Rulemaking seeking comment on the recommendation of the Federal-State Joint Board on Universal Service (Joint Board) that the Commission take immediate action to rein in the growth in high-cost universal service support disbursements. Specifically, the FCC sought comment on the Joint Board's recommendation that the Commission impose an interim, emergency cap on the amount of high-cost support that competitive eligible telecommunications carriers (ETCs) may receive. In a Public Notice released on the same day as the Recommended Decision, the Joint Board also recommended that both it and the Commission further explore comprehensive high-cost distribution reform, and sought comment on various reform proposals such as the use of reverse auctions, the use of geographic information systems (GIS) technology, the disaggregation of high-cost support, and support for broadband service.

F. Procedures for Processing Export Licenses, TAA Approval and Other Measures Concerning Commercial Satellites

1. The Government of the United States will continue its efforts to minimize delays and maximize transparency of procedures in export licensing and Technical Assistance Agreements (TAA) approval for commercial communications satellites in accordance with U.S. laws, regulations, and policies.

2. The Governments of the United States and Japan have conducted an earnest dialogue on export licensing for commercial satellites. Recognizing the importance of U.S.-Japan relations, the Governments of the United States and Japan will continue this dialogue on this issue.

G. Promotion of Trade in Telecommunications Equipment

1. In February 2007, the Governments of the United States and Japan concluded negotiations and signed a Mutual Recognition Agreement (MRA) relating to conformity assessment of telecommunications equipment.

2. In February 2007, the Governments of the United States and Japan also exchanged letters regarding an arrangement that would permit acceptance of results of conformity assessment for information technology (IT) equipment and industrial, scientific and medical (ISM) equipment conducted by accredited Japanese conformity assessment bodies with respect to Electro-Magnetic-Compatibility (EMC).

XIV. INFORMATION TECHNOLOGY

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 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*: The Government of the United States recognizes that TRIPS Article 14 and WPPT Article 6 provide for the protection for unfixed live sound performance works. The Government of the United States will ensure transparency regarding the protection for unfixed live sound performance works.

   b. *Protection of Rights of Unfixed Works*: The Government of the United States will ensure transparency regarding protection for unfixed copyrighted works under Federal and State law.

   c. *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.

   d. *Protection of Right of Rental Concerning Video Games*: The Government of the United States will continue discussions with the Government of Japan on the protection of the right of rental for computer programs with special emphasis on video game programs.

B. Response to Digital Networking

1. The Government of the United States recognizes that the efficient exploitation online of copyrighted works is important. The Government of the United States will continue to consider 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 will continue to exchange information with the Government of Japan on "access controls" and "copy controls" under section 1201 of the U.S. Copyright Act, which was added by the Digital Millennium Copyright Act (DMCA). The Government of the United States

takes appropriate measures through its triennial rulemaking proceeding to ensure that the protection of "access controls" will not adversely affect non-infringing uses by the public of copyright protected works, such as fair use of copyrighted works.

3. 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 the authorized use. Overlapping application of these rights causes concern for the Government of Japan that the usage of copyrighted works online is being impeded. The Government of the United States will ensure transparency regarding the protection of these rights.

4. The Government of the United States recognizes the importance of appropriate exceptions and limitations in the digital environment. The United States generally considers fair use and the balance between the rights of authors and the ability of users to avail themselves of the exceptions and limitations when introducing new laws related to copyright and related rights in the age of digitization and networking, and will provide appropriate information regarding new laws enacted by Congress that affect such an area.

5. The Government of the United States will provide the Government of Japan with appropriate, timely information regarding proposed legislation that may address the issue of "orphan works" (where the owner of the work cannot be identified and located by someone who wishes to make use of the work in a manner that requires permission of the copyright owner). The Government of the United States will consider relevant international obligations when establishing laws that address copyright protection for fashion designs and will also provide appropriate information of any such new laws.

C. **Spam**

1. The Governments of Japan and the United States share concern about spam, which has become a worldwide problem for businesses and consumers, as well as in the Information and Communications Technology sector.

2. The Government of the United States will continue to pursue a multifaceted approach to combating spam, including vigorous enforcement of the CAN-SPAM Act, public private partnerships, promoting industry-led technical solutions, international collaboration (including enforcement cooperation), and consumer education.

3. The Federal Trade Commission (FTC) has vigorously enforced the CAN-SPAM Act, bringing 26 cases alleging violations. Of the cases that have been resolved, courts have ordered defendants to pay more than $10.5 million in redress or disgorgement and $2.6 million in civil penalties.

4. The Department of Justice (DOJ) has prosecuted three additional spam-related cases, generating three guilty pleas and one guilty verdict.

5. The Government of the United States passed the U.S. SAFE WEB Act, which went into effect in December 2006. The Act will allow the FTC to cooperate more fully with foreign law enforcement authorities in the area of cross-border fraud and other practices harmful to consumers that are increasingly global in nature, including spam.

6. Specifically, the U.S. SAFE WEB Act enhances FTC authority in four areas that are essential to cross-border enforcement cooperation.

   a. The Act authorizes the FTC to share confidential information, such as documents and testimony, with appropriate limitations and assurances of confidentiality, with its foreign law enforcement counterparts to help the FTC's law enforcement efforts and U.S. consumers.

   b. It permits the FTC to use its investigative power on behalf of foreign law enforcement agencies if it determines that the cooperation is consistent with its policy goals and resources.

   c. The Act permits the FTC to protect the confidentiality of information it receives from foreign agencies.

   d. The Act contains several provisions that will strengthen the FTC's bilateral and multilateral enforcement relationships, such as permitting the FTC to enter into international cooperation agreements and staff exchanges with foreign counterparts.

7. The U.S. SAFE WEB Act also confirms the FTC's authority to take action in cross-border cases and obtain remedies, including restitution, for injured U.S. and foreign consumers.

8. The Government of the United States will continue to explore and consider measures to combat spam with the Government of Japan.

XV. MEDICAL DEVICES AND PHARMACEUTICALS

A. **Regular Meetings with Japanese Companies Operating in the United States**: The U.S. Food and Drug Administration, Department of Health and Human Services (FDA/HHS), will continue to provide opportunities to meet with Japanese companies operating in the United States. Appropriate FDA/HHS experts are made available for such meetings based on the issues stated in the request.

B. **Facilitation of Worldwide Simultaneous Development**: The U.S. Department of Commerce will continue to encourage U.S. industry to work with Japanese regulators to facilitate worldwide simultaneous development of drugs, including in Japan.

C. **Establishment Inspection Reports**: FDA/HHS routinely provides a copy of the Establishment Inspection Report to the responsible individual of an inspected firm (from any country, including Japan), when an FDA internal review is complete and the inspection is deemed closed.