

**SEVENTH REPORT TO THE LEADERS ON THE
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE
July 5, 2008**

The U.S.-Japan Regulatory Reform and Competition Policy Initiative was launched in 2001 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. This Report is the seventh under this Initiative.

The Initiative is a two-way dialogue between the Governments of the United States and Japan. Both Governments exchanged recommendations in October 2007, following which four Working Groups established under this Initiative met to discuss reform in key sectors and areas such as intellectual property, distribution and customs procedures, competition policy, trade and investment-related measures, consular affairs, medical devices and pharmaceuticals, commercial law, privatization of public entities, and telecommunications/communications. The High-Level Officials Group also met in May 2008 to advance progress on a range of issues raised under this Initiative.

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

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

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

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REGULATORY REFORM AND OTHER MEASURES BY
THE GOVERNMENT OF JAPAN

On the occasion of the annual meeting of the World Economic Forum in Davos in January 2008, Prime Minister Fukuda expressed Japan's intention to advance work toward market liberalization, including through new reforms in the area of foreign direct investment in Japan. In accordance with this basic policy direction outlined by Prime Minister Fukuda, the Government of Japan is pursuing a variety of measures.

This work includes a series of new policy steps endorsed by the Council on Economic and Fiscal Policy (CEFP) in June 2008, when it concluded its "Economic Growth Strategy." The Economic Growth Strategy seeks to strengthen Japan's growth potential in line with an open country policy of developing along with the global economy. This Strategy also incorporated measures proposed in May 2008 by the Expert Committee on FDI Promotion to help drastically expand direct investment into Japan. The Economic Growth Strategy was subsequently included in the Cabinet's "Basic Policies for Economic and Fiscal Reform 2008," approved in June 2008.

The Government of Japan is also considering and pursuing other reform-oriented measures. The Expert Committee on Structural Changes and the Japanese Economy, established under the CEFP, issued a report in July 2008 outlining the type of 'economic society' that Japan seeks over the coming decade in the global economy and setting a course toward it. In addition, the Council for the Promotion of Regulatory Reform (CPRR) issued an interim report in July 2008 in preparing to compile its third recommendations to the Government by the end of 2008. The Government of Japan will continue to actively advance regulatory reform, taking into account discussions and recommendations by the CEFP, the CPRR and the Expert Committee on FDI Promotion.

I. COMMUNICATIONS

A. Promotion of Competition

1. In October 2007, the Ministry of Internal Affairs and Communications (MIC) revised the "New Competition Promotion Program 2010", formulated in September 2006 as a detailed road map to develop an environment for fair competition in the broadband market, to respond appropriately to the rapid changes in the market environment. Based on this program, MIC has taken into consideration measures, such as (i) Review of Designated Telecommunications Facilities System (Dominant Regulations), (ii) Review of Calculation Method for Interconnection Charges, (iii) Competition Promotion in the Mobile Communications Market, (iv) Review of Universal Service System, (v) Development of Environments Intended to Ensure Network Neutrality, (vi) Enhancing Consumer Protection Measures, and is in the process of implementing measures in the order that they are concluded.
2. In May 2008, MIC revised the "Guidelines Concerning Applications of the Telecommunications Business Law and the Radio Law Pertaining to Mobile Virtual Network Operators (MVNO)" to promote market entry into the MVNO

business. These Guidelines were based on the “Mobile Business Revitalization Plan” which MIC released in September 2007 in order to develop an open mobile business environment that promotes the proliferation of diverse business models, to further revitalize the mobile business market, and to improve user benefits.

3. MIC has implemented the Competition Safeguard System to periodically verify the scope of designated telecommunications facilities and validity of fair competition requirements concerning the NTT Group since FY 2007. In February 2008, MIC released the results of verification (FY2007) and requested NTT East and West to take necessary measures in light of the results of the verification. This request was made to ensure fair competition in the telecommunications business, through an approach which requires NTT East and West to fully inform their subsidiaries not to use information acquired through required trustee business by NTT East/West and NTT DoCoMo for the purposes other than those for which it was originally intended, and also requires them to enforce this request.
4. In January 2008, the Information and Communications Council was consulted to deliberate on the interconnection charge for optical subscriber lines for FY 2008 and onward. The Council is deliberating applications from NTT East and West for revised charges with reductions from those for FY 2001 to FY 2007 of 9.1 percent for NTT East and 2.8 percent for NTT West.

B. Fixed Interconnection

1. Long-Run Incremental Cost (LRIC): In February 2008, MIC revised the Rules for Interconnection Charges regarding the calculation method for interconnection rates on the basis of the LRIC Model applicable in FY2008 and onward, taking into consideration opinions submitted through the public comment procedure and the report from the Information and Communications Council. In March 2008, MIC authorized interconnection rates for FY2008 calculated based on the revised rules, which began to be applied in April 2008. As a result, GC interconnection was set at 4.53 yen per 3 minutes, a decrease of 3.4 percent compared to the previous fiscal year; and IC interconnection was set at 6.41 yen per 3 minutes, a decrease of 2.1 percent compared to the previous fiscal year.
2. Next-Generation Network (NGN): In March 2008, the Information and Communications Council reported the "Next-generation network interconnection rules" based on the deliberation and opinions submitted through the public comment procedure. The report includes recommendations that it is necessary to designate NGNs of NTT East and West as Category I Designated Telecommunications Facilities and to impose unbundling obligation on such networks.

C. Mobile Interconnection

1. 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 2008 that the average interconnection rate between the rate within the same NTT DoCoMo service area and the rate for a subscriber located in a distant NTT DoCoMo service area was revised at 11.0 yen per minute, a decrease of 2.1 percent compared to the previous fiscal year.

2. In March 2008, MIC revised the Rules for Telecommunications Business Accounting to separate incentives for the sale of terminals and incentives for the sale of communications services in accounting cost. In April 2008, MIC released the "Accounting Operation Guideline for Sales Incentives in Telecommunications Business" to ensure proper implementation of the rules, with a view to contributing towards clear determination of the telecommunications service cost, and with the expectation that the costs on which interconnection charges and wholesale telecommunications service prices are based will be calculated appropriately with the accounting methodology of this guideline.
3. In November 2007, regarding the case concerning the interconnection of telecommunications facilities between NTT DoCoMo and Japan Communications Inc., the Minister for Internal Affairs and Communications issued an award, deciding that setting of user charges should be "end-to-end charges" and it is appropriate that Japan Communications Inc. has the right to set the user charges.

D. Promotion of Advanced Technologies and Services

1. In December 2007, MIC revised the "Frequency Assignment Plan" for 90-108MHz and 170-222MHz in the VHF band and 710-770MHz in the UHF band, which will be vacated after the digitization of analog terrestrial television broadcasting, to make it available for "Broadcasting" including multimedia broadcasting to mobile devices, "Private Communication Systems" that realize broadband communication for ensuring public safety and security, "Telecommunications" including mobile phones and "Intelligent Transport Systems (ITS)"
2. For the introduction of broadband mobile wireless access systems using the 2.5 GHz band, in December 2007, MIC approved the establishment plans submitted by Wireless Broadband Planning K.K. and Willcom, Inc., and assigned spectrum to them.

E. Promotion of Trade in Telecommunications Equipment

1. Mutual Recognition Agreement:
 - a. The Agreement on Mutual Recognition of Results of Conformity Assessment Procedures between Japan and the United States of America entered into force on January 1, 2008. The Governments of the United

States and Japan are making preparations towards implementing the agreement, including training in technical requirements, as soon as possible.

- b. Under the arrangement for the acceptance of results of conformity assessment for information technology (IT) equipment and industrial, scientific and medical (ISM) equipment with respect to Electro-Magnetic Compatibility (EMC), 58 Japanese conformity assessment bodies (CABs) have been recognized by the Federal Communications Commission (FCC) and 19 U.S. CABs have been recognized by the Voluntary Control Council for Interference by Information Technology Equipment (VCCI) by the end of May 2008.
2. In October 2007, MIC amended regulations to provide for the registered certification body to be able to assign, at its own discretion, the same number for a new certification when making changes in the construction type for an addition of or a change of antennas for the radio equipment of radio stations of a low-power data communication system (wire-less LAN) based on an already certified construction type.

II. INFORMATION TECHNOLOGIES (IT)

A. IT and e-Commerce Policymaking

1. Developing IT Policy Plans: The Government of Japan will seek and consider a diverse range of opinions from the private sector when creating and implementing IT and e-Commerce policies. In July 2007, the IT Strategic Headquarters (ITSH) released a new IT Priority Policy Program that was published on the Cabinet Secretariat's website. The ITSH will continue to seek opinions from interested parties, including through an Expert Committee on IT Strategy Evaluation that includes private sector members, by employing public comment procedures. The ITSH will release a new Priority Policy Program in summer 2008.
2. Facilitating Private Sector Input: The ITSH will provide a public comment period for a draft of the Priority Policy Program. 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 policies through public comment procedures and other means. The Government of Japan also will continue to provide opportunities for the private sector to obtain information promptly about, and participate actively in, the formation and work of IT and e-Commerce advisory and study groups.
3. Fostering Technology Neutrality: The Government of Japan will implement laws, regulations, and guidelines related to IT in a manner that promotes choice and competitive market conditions by ensuring that providers and users have the flexibility to choose technologies that best suit their needs. The Government of

Japan also will continue to cooperate closely with the private sector on international standards development and, when appropriate, use established international standards when formulating IT and e-Commerce policies, guidelines, and regulations.

4. Promoting International Compatibility: The Government of Japan understands that it is important to foster an environment that 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*: In adherence to the 2008 Intellectual Property Strategic Plan, the Government of Japan will continue to consider in a timely manner 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 provide the United States updates to its deliberative process.
- b. *Copyright Term Extension*: In adherence to the 2008 Intellectual Property Strategic Plan, the Government of Japan will continue its deliberations in a timely manner 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 provide the United States updates to its deliberative process. 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 considered whether the requirement of a complaint from an injured party for prosecution of copyright crimes under the copyright law should be modified. As the result of its deliberation in FY2007, the Council for Cultural Affairs confirmed that a careful approach is necessary in consideration of various factors, such as social influence, prior to making a decision. The Council for Cultural Affairs also found that there was no acknowledgement that the requirement of the right holders' complaint for copyright crime was a serious obstacle to investigation. The Government of Japan notes the Government of the United States' view that ex officio authority is an important tool for facilitating effective investigation and prosecution of copyright crimes.

2. Online Piracy: The Government of Japan has exchanged information concerning

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

3. Protection of Digital Content: The Government of Japan has developed appropriate internal regulations and decrees to forbid copyright infringement in its governmental operations that address the misuse of file-sharing technologies and protect intellectual property, software and other digital content assets used. The Government of Japan will continue to exchange information on the protection of digital content with the Government of the United States and consider opinions from right holders in future studies on the effects of digitalization and networking on the Japanese copyright system. The Government of Japan will continue to apply its private reproduction exception in a manner consistent with its international agreements.
4. IP Multicasting Statutory License: The Government of Japan has confirmed that the revision to this law 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 WIPO (World Intellectual Property Organization) Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (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.
5. Exceptions to Copyright Protections Affecting Publishers: The Government of Japan has issued guidelines and presented examples of the “educational exceptions” in article 35 of the Copyright Law for educational institutions, teachers, and students through related organizations to clarify the limitations of the exception under the amended Copyright Law. The Government of Japan will continue to ensure that the application of Article 35 of Japan’s Copyright Law does not conflict with the normal exploitation of copyrighted works and does not unreasonably prejudice the legitimate interests of right holders, and that any additional proposed copyright exceptions that affect scientific, technical, medical or education publishers are carefully studied on the same grounds and consider opinions from right holders in the process. The Government of Japan recognizes the position of the Government of the United States to encourage market-based solutions.
6. Technical Protection Measures: The Government of Japan recognizes the Government of the United States’ concern regarding the provision of effective civil and criminal remedies for unauthorized circumvention of access controls, and all forms of trafficking in devices or services to circumvent technological protection measures. The Government of Japan will also continue to update the

Government of the United States about its study of “access controls.”

7. Patent Procedures:

- a. *12-Month Grace Period:* The Government of Japan will continue to discuss the issue of a 12-Month Grace Period as a package of the international patent harmonization at multi-national fora with the Government of the United States.
- b. *Patent Application Prosecution:* Each patent application is examined in line with the examination guideline which provides that all of the reasons for refusal should be notified in the first notice of reasons for refusal.

8. Trademarks: The Governments of Japan will continue to work closely with the Government of the United States on trademark matters through the Trademark Trilateral and other relevant fora.

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

1. At the Japan-U.S summit held in April 2007, the Governments of Japan and the United States affirmed to strengthen Japan-U.S. cooperation on IPR issues, and continue to closely cooperate to strengthen IPR protection and enforcement around the world.
2. Japan-U.S. cooperation to strengthen IPR protection and enforcement around the world has achieved numerous concrete results, including the advancement of discussion on the Anti-Counterfeiting Trade Agreement (ACTA), hosting a private-public conference between the United States, Japan and EU in Thailand in April 2008 to promote anti-counterfeiting and piracy in South East Asia under the Department of Commerce (DOC)-Ministry of Economy, Trade and Industry (METI) initiative, efforts to streamline and harmonize the International Patent System such as the full implementation of the Patent Prosecution Highway (PPH) in January 2008, and efforts by Asia-Pacific Economic Cooperation (APEC) in 2007 to improve IPR border enforcement and streamline the patent application process. The Government of Japan is participating as a third party in the procedures of World Trade Organization (WTO) dispute settlement brought by the United States concerning China’s measures on IPR protection and enforcement.
3. 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.
4. The Government of Japan will continue to work together with the Government of the United States in accelerating the negotiation on establishing a strong ACTA and striving to complete the negotiations by the end of 2008.

5. The Government of Japan will continue to use the APEC forum 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 will work together closely with the Government of the United States to ensure strong deliverables this year, and will continue to cooperate in all other appropriate international fora, including the WTO, to advance protections for IPR.

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

1. A Subcommittee under the Council has started a new term of discussion to examine next measures regarding the implementation of the Privacy Act. The review of the Basic Policy on the Protection of Personal Information was completed in April 2008 and measures such as public relations activities to prevent overreaction are being implemented, and the Council is considering standardization efforts for guidelines. The Cabinet Office will continue to carefully consider the opinions of the Council.
2. In addition, the Council emphasized in the Summary that the Government of Japan should take necessary measures for the standardization of various implementation guidelines. In light of this opinion, in April 2008, the Cabinet Office began discussion on the standardization of the 37 guidelines in 24 sectors (as of April 1, 2008) for the purpose of promoting the protection of personal information with the goal of integration and consistency throughout Government, and will take necessary measures in considering the circumstances of various business sectors.
3. The Governments of Japan and the United States share the view that it is important to provide effective protections for individuals’ personal information while ensuring efficient cross-border data flows. In recognition of these principles, and the value of a flexible privacy approach, the Governments of the United States and Japan will continue to participate in multilateral fora such as the Organization for Economic Cooperation and Development (OECD) and APEC to exchange information and generate consensus on issues such as privacy.

E. **Health IT and e-Accessibility**

1. Health IT:
 - a. *New Grand Design:* The Ministry of Health, Labour and Welfare (MHLW) will implement its “Grand Design” for the Use of Information Technologies in the Medical, Healthcare, Nursing, and Social Welfare

Fields” (new Grand Design). The new Grand Design indicates Japan’s vision for what health IT can achieve, such as the complete online systematization for the transfer of itemized statements of medical expenses.

- b. *Incentives to Use Health IT:* On April 1, 2008, MHLW increased incentives for doctors and hospitals to use innovative health IT that facilitates information sharing by, for instance, raising reimbursement levels for use of picture archiving and communication systems. This increase can spur development of health IT, which can improve the health of patients and the efficiency of the healthcare system.
- c. *Encouraging a Range of Vendors in Government-Sponsored Health IT Projects:* The Government of Japan will encourage a wide range of qualified IT vendors to participate in government-sponsored projects that develop or showcase health IT systems. Each ministry will continue to post information on its website about government-sponsored projects used to develop or showcase health IT systems prior to fully launching such projects or soliciting participation in them. The Ministry of Economy, Trade and Industry (METI) is committed to posting information on its website about procurements for government-sponsored projects and accepting participation in them by a wide range of qualified vendors. METI posted information on its website about procurement for the medical information network it sponsors in the Tokai region.
- d. *Improving Transparency and Stakeholder Involvement in Policymaking:* The Government of Japan will continue to provide meaningful opportunities for interested parties including the private sector to present their views on health IT proposals, policies, and rules, and participate in relevant health IT working groups and advisory panels. For example, when a review of the new Grand Design becomes necessary in the future, MHLW will hold broad discussions with the national public and interested parties.
- e. *Promoting Harmonization with International Standards:* The Government of Japan will ensure its work on standards for health IT systems promotes harmonization with international standards paying due attention to the principle of technology neutrality. MHLW and METI promote interoperability by supporting “connect-a-thons” in which the interoperability of health IT equipment is tested. METI provided information online about the connect-a-thons, which is one of the projects aiming to develop interoperability for health information systems in Japan. MHLW is providing financial support to develop the tool used for the connect-a-thons. METI also provided information online about the new Health-IT project, in which METI will cooperate closely with MHLW and the Ministry of Internal Affairs and Communications. The new project will develop information infrastructure that people can use to easily collect

and store their own health information, and effectively utilize it to promote their health.

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. The Governments of Japan and the United States will continue to exchange 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, as appropriate.

F. **Government IT Procurement Reform**

1. Enforcing the Basic Policy: By autumn 2008, the Cabinet Secretariat will publish a report that measures compliance with and monitors the implementation of the “Basic Policy for the Public Procurement of Computer Systems” (Basic Policy). The government procuring authorities have executed IT procurements based on the Basic Policy. The Ministry of Internal Affairs and Communications (MIC) compiled and distributed 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. A report on the survey will be posted on the Cabinet Secretariat’s website.
2. Improving Communication with the Public: By April 1, 2009, 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) will be expanded to include items such as procurement plans and specifications and information on bid announcements and procurement practices. The Government of Japan will use the database to accumulate data on procurement cases that ministries can reference, and to monitor compliance with guidelines for government IT procurement. In FY2007, MIC received and now is analyzing 10 reports from ministries on their IT procurement. Ministries are required to file such reports when they procure IT in amounts exceeding 0.8 million SDR (140 million yen). The Government of Japan will ensure that ministries file reports on all procurements that exceed the threshold, and the online database will be used to clarify the current situation concerning IT procurement including the use of non-competitive contracts.
3. Ownership of Intellectual Property: The Ministry of Economy, Trade and Industry (METI) will implement, and request other ministries to implement, the April 2007 amendment to the Industrial Technology Enhancement Act (the Act) to make it possible for contractors to own intellectual property rights concerning software developed through government-sponsored programs. Ministries can implement the Act at their own discretion. In August 2007, METI instituted the “Guideline for

the Japanese Bayh-Dole Act related to Software” (Guideline), and is informing each ministry about it. METI published on its website information to enhance compliance with the Act including items that should be written into contracts such as the attribution of intellectual property rights. METI also published on its website a model contract that clarifies the rights and obligations of vendors and government ministries. The MIC-compiled manual (*jitsumu tebikisho*) for implementing the Basic Policy stipulates that the Guideline should be referred to when necessary.

4. Limiting Vendor Liability: In FY2008, MIC will conduct outreach to help other Government of Japan agencies understand the Basic Policy’s requirement that the liability of vendors in government IT procurement contracts should be clearly defined and appropriately limited. In September 2007, MIC added a model contract to the manual (*jitsumu tebikisho*) to help other Government of Japan agencies understand the Basic Policy’s requirement that the liability of vendors in government IT procurement contracts should be clearly defined and appropriately limited.
5. Promoting Competitive Bidding: On August 10, 2007, Japan’s Cabinet decided that incorporated administrative agencies should engage in competitive bidding, in principle, and required them to develop action plans on their use of competitive bidding. The Government of Japan will review how frequently incorporated administrative agencies use non-competitive contracts. The Government of Japan also notified local governments of the Basic Policy regarding the use of competitive bidding.
6. Eliminating Backdating: The Government of Japan will enforce the Basic Policy’s prohibition of the backdating of contracts. MIC operates an office that can receive complaints about backdating of contracts and can follow up by contacting relevant ministries.

III. MEDICAL DEVICES AND PHARMACEUTICALS

A. **Changes in the Japanese Healthcare System**: As the Ministry of Health, Labour and Welfare (MHLW) and its 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.

B. **Medical Device and Pharmaceutical Pricing Reform and Related Issues**: The Government of Japan will consider development of innovative medical devices and pharmaceuticals as follows based on the revision of pricing system in April 2008:

1. Pharmaceuticals:

- a. *Encouraging U.S. Industry Input*: In 2007, the Government of Japan held three meetings of the Government-Private Sector Dialogue for Innovative

Drug Discovery in order for leaders of industry, Government, and academia, including U.S. industry, to share views on policies to foster innovation in the pharmaceutical field and enhancement of international competitiveness in the industry. The Government of Japan expanded this framework to include the medical device industry (including the U.S. medical device industry), and held the first meeting of the newly expanded “Government-Private Sector Dialogue for Discovery of Innovative Drugs and Medical Devices” on April 24, 2008. The meetings are currently planned to be held once or twice a year. In addition, MHLW will continue to select suitable candidates, irrespective of nationality, to serve as members of the Drug Pricing Expert Subcommittee of *Chuikyo*.

- b. *Repricing Based on Market Expansion*: MHLW notes that the U.S. Government continues to express strong opposition to the market-expansion repricing rule. MHLW will continue to discuss with industry, including U.S. industry, the issue of repricing based on market expansion.
- c. *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.
- d. *Using Appropriate Comparators*: In view of the situation in Japan where appraised prices for new pharmaceuticals are sometimes lower than foreign average prices, MHLW agreed in December 2007 to use as comparators drugs, in principle, that have been on Japan’s pharmaceutical pricing list for less than 10 years and that do not have competition from generic products.
- e. *Foreign Price Adjustment (FPA) Rule*: To ensure that innovation is appropriately rewarded, MHLW uses the most recent foreign drug price data available to the public if it is not listed in the newest annual edition of the commonly used price book.
- f. *Pricing System Reform*: MHLW will consider the views of industry, including U.S. industry, to ensure the reimbursement pricing system facilitates the access of patients to innovative drugs. MHLW provides industry, including U.S. industry, with ongoing opportunities to express opinions on proposals regarding the pharmaceutical pricing reform in Japan, including industry proposals to revise the pricing system which would improve economic returns for patented drugs during their patent life or exclusivity period and gives those opinions consideration.

- g. *Expanding Input at Drug Pricing Organization (DPO) Meetings:* In February 2008, *Chuikyo* agreed to allow drug manufacturers to present at initial DPO meetings their views on drug prices, regardless of whether the drug manufacturers seek an adjustment to premiums.
- h. *Prescription Period for New Drugs:* MHLW notes industry's proposals regarding the prescription period for new drugs.
- i. *Insurance Coverage for Procedures and Tests for the Appropriate Use of Pharmaceuticals:* MHLW will continue to consider in light of opinion from medical experts and others the appropriate coverage under the National Health Insurance System of procedures and tests required for the appropriate use of pharmaceuticals. MHLW will be open to discussing the views of industry, including U.S. industry, on procedures and tests required for the appropriate use of pharmaceuticals.

2. Medical Devices:

- a. *Functional Categories:* In the medical device pricing revision of 2008, MHLW divided some existing functional categories and added new categories to reflect product differences in light of the actual conditions of clinical use. As of April 2008, reimbursement prices can be increased for functional categories of medical devices determined to be in extremely short supply. MHLW will be open to discussing proposals from industry, including U.S. industry, on functional categories.
- b. *The Foreign Average Price (FAP) Rule for Medical Devices:* MHLW recognizes that the FAP rule has narrowed foreign price differences. In the medical device pricing revision of 2008, MHLW used only industry-supplied data on the four comparator countries, maintained a maximum price cut of 25 percent, reduced the functional categories affected, and decided to phase in the cuts. MHLW provides industry, including U.S. industry, with opportunities to express opinions regarding the components of the foreign average price reference system, including the number of functional categories to which the foreign average price reference system of medical devices is applied and the data used in maximum price cut rules and price calculations. MHLW notes that the U.S. Government expressed its view that the FAP rule should not be applied more strictly in the future.
- c. *Medical Device Pricing:* MHLW will continue to provide industry, including U.S. industry, with ongoing opportunities to express opinions on proposals regarding the medical device pricing reform in Japan.
- d. *Evaluation of Innovation:* In the medical device pricing revision of 2008, in order to strengthen incentives for the development and practical application of new and improved medical devices, MHLW reviewed

reimbursement price adjustment premiums, restructured and consolidated usefulness premiums (I) and (II), and created “improvement” premiums. In the medical device pricing revision of 2008, MHLW established two new ways to qualify for the “effectiveness” premium for medical devices. As a result, devices that are less invasive than other products and pediatric devices that are smaller or lighter than products for adults now qualify for the effectiveness premium. MHLW also increased the minimum level of the “epochal function” premium to 50 percent from 40 percent. MHLW will be open to discussing proposals from industry, including U.S. industry, on evaluation of innovation.

- e. *C1 and C2 Pricing*: To promote prompt access to medical devices for patients, the listing of products in the C2 category has been quarterly since the medical device pricing revision of 2006. In 2008, with regard to medical devices classified into the C1 category, which had been “limited to those classified within three months before the commencing month of insurance application,” MHLW substantially shortened the waiting time by limiting the listing “to those classified within one month before the commencing month of insurance application.” In addition, since the medical device pricing revision of 2008, companies can express views at meetings of the Special Organization for Insured Medical Materials before the organization makes a draft decision regarding the functional category to which a product will be assigned. In the past, companies could attend such meetings only after the draft decision had been made. MHLW will be open to discussing proposals from industry, including U.S. industry, on C1 and C2 pricing procedures.
- f. *In-Vitro Diagnostics (IVDs)*: MHLW held a study group (*benkyokai*) for issues related to in-vitro diagnostics (IVDs) with industry, including U.S. industry, in 2007 and has addressed some of the study group’s proposals in the medical device pricing revision of 2008. In the 2008 reimbursement revision, the Government of Japan increased the technical fee reimbursement for “quick testing” in hospitals and other testing fees. MHLW will continue to provide industry, including U.S. industry, with ongoing opportunities to express its opinions.
- g. *Diagnostic Imaging Techniques*: In the medical reimbursement revision of 2008, *Chuikyo* agreed to increase reimbursement for use of coronary CT scans and cardiology-related MRI scans. MHLW will continue to evaluate properly advanced diagnostic imaging equipment and techniques.

- 3. Blood Products: MHLW will continue to 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**: The Government of Japan is striving to eliminate the lag in the introduction in Japan of

innovative medical devices and pharmaceuticals. The Government of Japan will improve its regulatory system by taking the following actions in FY2008:

1. Pharmaceuticals:

- a. *Promoting Simultaneous Global Development of Drugs:* To promote simultaneous global development of medicines, MHLW published guidelines called “Basic Principles on Global Clinical Trials” in September 2007 and has been making efforts to improve the environment for implementing clinical trials. The Government of Japan supports simultaneous global development of pharmaceuticals as a means to eliminate the drug lag. MHLW and the Pharmaceuticals and Medical Devices Agency (PMDA) will continue to exchange opinions with related parties, including U.S. industry, to facilitate Japan’s participation in simultaneous global development.
- b. *Improving Drug Clinical Trials:* Based on the “New 5-Year Clinical Trial Activation Plan,” implemented since April 2007, MHLW has been taking such measures as the designation of 10 Core Clinical Research Centers and 30 Major Clinical Trial Institutions to stimulate clinical trials and enhance clinical trial operations. In addition, MHLW revised the ministerial ordinance for Good Clinical Practices, including provisions related to the clinical trial review boards, to ensure smoother operation of clinical trials. PMDA plans to increase clinical trial consultations for new drugs to about 420 cases a year, up from about 280 cases in FY2007.
- c. *Cooperation with Industry on Ethnic Factors Study Group:* The National Institute of Health Sciences appointed experts from industry, including U.S. industry, to the study group on ethnic factors in clinical data from East Asian populations. MHLW encourages industry, including U.S. industry, to submit relevant clinical data that industry develops in the course of its usual studies.
- d. *Maintaining a Dialogue with Industry on User Fees and Agency Performance:* PMDA and MHLW will continue to exchange opinions with industry, including U.S. industry, on user fees and their implementation of consultations, reviews, and approvals. PMDA will continue to provide performance data on its reviews and consultations to industry, including U.S. industry.
- e. *Increasing Drug Reviewers:* MHLW will ensure that PMDA implements its plan to increase by 236 the number of drug reviewers by March 31, 2010, and that PMDA redoubles efforts to improve the systems of evaluating pharmaceuticals and conducting clinical trial consultations. As of May 1, 2008, PMDA had 276 reviewers for drugs and medical devices, an increase of 70 reviewers, including 63 drug reviewers and 7 device

reviewers, from the year before. PMDA employed 241 drug reviewers as of May 1, 2008. As of April 1, 2008, 22 of PMDA's drug and device reviewers were physicians and 10 were biostatisticians. MHLW will encourage PMDA to broaden its expertise by increasing its hiring of reviewers who are physicians with clinical experience or who are biostatisticians. Since October 2007, PMDA has been allowing reviewers newly hired from the drug industry to engage in all the operations of PMDA immediately after entering PMDA, except when the operation is related to the business of the companies at which they worked within five years before their employment at PMDA. As of February 1, 2008, PMDA employed 16 former drug company employees.

- f. *Discussing the Unapproved Pharmaceuticals Committee:* MHLW has explained to U.S. industry and the U.S. Government the operations of the Committee on Issues Related to Use of Unapproved Pharmaceuticals.
- g. *Reducing Review Times for Post-approval Changes:* MHLW and PMDA will exchange views with industry, including U.S. industry, on reducing review times for partial changes, including manufacturing changes. MHLW and PMDA will continue to improve PMDA's review activities, including those related to post-approval changes.
- h. *Reducing MHLW's Approval Processing Times:* MHLW will exchange views with industry, including U.S. industry, on reducing the processing time for new drug applications before issuing final approvals.
- i. *Improving Vaccine Reviews and Promotion:* MHLW has established a study group to create guidelines on vaccines and promote the use of vaccines. The Government of Japan will continue to exchange views with industry, including U.S. industry, on improving vaccine reviews.

2. Medical Devices:

- a. *Task Force on Reviews and Approvals:* MHLW, PMDA, and industry, including U.S. industry, have organized a working-level task force to discuss issues such as using accelerated stability testing data, clarification of situations where partial change applications or minor change notifications are required, including the possibility of allowing a partial change application during the review of a previous partial change application for the same device. MHLW and industry will continue to discuss requests for information for ensuring the safety and biocompatibility of raw materials with a view toward streamlining reviews and approvals and alleviating the device lag. MHLW issued a notification regarding examples of minor changes in September 2007. MHLW will clarify to industry situations in which minor changes require an approval or when a company notification is sufficient. MHLW and PMDA have

been studying whether the real-time review process used by the U.S. Food and Drug Administration can be used for some of the changes that require prior review and approval.

- b. *PMDA's Performance Objective:* MHLW will continue to provide meaningful opportunities to industry, including U.S. industry, to address its views regarding the next mid-term plan, including issues related to performance goals and user fees to steadily improve PMDA's review times. PMDA will continue to release data that allows industry, including U.S. industry, to assess PMDA's performance. PMDA increased its medical device reviewers to 35 as of April 2008.
- c. *Accelerated Stability Test Data:* MHLW intends to issue a notification on accelerated stability test data for device approvals where accelerated testing methods are validated by scientific evidence. The notification will contain examples on the appropriate uses of such data.
- d. *Protecting Business Confidential Information:* MHLW will ensure that business confidential information of companies is protected when the summary of technical documentation for new medical device applications is published by MHLW following approval of those applications. PMDA is developing guidance on handling the disclosure of this business confidential information in consultation with industry, including U.S. industry.
- e. *Raw Material Data Requirements:* In FY2007, a government-industry task force began discussing Japan's requirements for data on raw materials in medical devices, with a view toward streamlining reviews and approvals. MHLW continues to work with industry, including U.S. industry, to further streamline the raw material requirements with due consideration for safety.
- f. *Accreditation of Foreign Manufacturers:* MHLW and PMDA have published instructions for industry on the application for Accreditation of Foreign Manufacturers both in Japanese and English in order to encourage industry to file valid applications for faster processing. MHLW will discuss with industry, including U.S. industry, industry's concerns and proposals regarding the accreditation of foreign manufacturers.
- g. *Improving the Efficiency of the Factory Inspection Program:* To improve the efficiency of PMDA's factory inspection program, PMDA and MHLW will consult with industry, including U.S. industry, to streamline quality management system conformity assessments.
- h. *IVD Approvals:* In FY2007, MHLW, PMDA, and industry, including U.S. industry, established a working-level task force to exchange opinions concerning IVDs, including issues related to determination of shelf-life

and approaches to regulation of IVDs.

D. Blood Products

1. Providing Opportunities for Input: MHLW will continue to provide industry, including U.S. industry, with meaningful opportunities to discuss the supply and demand plan, the labeling requirements of *kenketsu* and *hikenketsu*, and other blood products regulatory matters through the twice-yearly meetings.
2. Expediting “Partial Change” Approvals: MHLW and PMDA will exchange views with industry, including U.S. industry, on reducing review times of “partial changes” of blood products.

E. Over-the-Counter (OTC) Medicines: In association with pharmaceutical marketing system reforms, MHLW announced in a notification the new risk classifications for over-the-counter (OTC) medicines in April 2007. MHLW will establish, revise, and enforce other ministerial ordinances for the OTC medicine marketing system including the contents of claims through June 2009. MHLW will exchange opinions on the establishment and implementation of the system and on other issues with related parties, including U.S. industry.

F. Nutritional Supplements

1. Regulatory Categories and Claims:
 - a. The nutritional supplement system in Japan is set in accordance with the guidelines of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and decided in the light of the actual intake values of the people. MHLW continues to make efforts to improve the system for food with health claims based on the outcomes of reviews in the CCNFSDU. MHLW recognizes increased interest from the Diet and from industry for a new regulatory category for nutritional supplements. MHLW will continue to exchange views with industry, including U.S. industry, on each side’s position on a system to allow ingredient-specific health claims that is both transparent and based on scientific principles.
 - b. MHLW will continue to provide appropriate opportunities for input to industry, including U.S. industry, and will take into consideration guidelines developed by the Codex Alimentarius Commission and its committees during the development and revision of regulations relevant to nutritional supplements. MHLW continues to make efforts to improve the system for Foods for Specified Health Uses (FOSHU) based on outcomes of reviews in the CCNFSDU.
 - c. MHLW will continue to work with industry to establish a system by the end of FY2008 or earlier to provide consumers with accurate information

from the database of the National Institute of Health and Nutrition based on the recommendations of the Office of Trade and Investment Ombudsman (OTO).

2. Health Food Safety Regulations:

- a. In July 2007, MHLW established a Study Group on Ensuring the Safety of Health Foods and provided opportunities for input to interested parties, including U.S. industry.
- b. With a view toward ensuring fairness and transparency, MHLW will continue to provide appropriate opportunities for input to industry, including U.S. industry, during the development, revision, and implementation of safety regulations related to health foods.
- c. MHLW clarifies the process by which a new ingredient is designated as a food ingredient, a drug ingredient, or a food additive with prior consultation opportunities at the quarantine stations. MHLW will continue to provide opportunities for industry to exchange views and to ask questions about the application process and classification criteria for new ingredients.

3. Food Additives:

- a. The Government of Japan will continue to make efforts to designate food additives in the most efficient way possible.
- b. The Government of Japan recognizes the importance of international harmonization in the area of food additives. (*Also see section "Food Additives" under Other Government Practices on page 50.*)
- c. MHLW will continue to improve the process for clearing shipments that have been stopped at quarantine stations due to naturally occurring traces of substances classified as food additives, such as benzoic acid and sorbic acid. Steps include increasing training for quarantine station officers and developing a central reference database where officers and importers can find research studies and cases where these substances occur naturally in food products. MHLW will also consider proposals to address this issue systematically.
- d. MHLW continues to provide requests for additional information in writing when deemed necessary and appropriate. If a company is not able to resolve an issue with a quarantine station, the company may contact the relevant section at MHLW for assistance.

4. Import Issues:

- a. MHLW has been promoting the efficiency of procedures at quarantine stations by improving the sharing of documents and information.
- b. MHLW strives to ensure consistency in instructions given during prior consultations. MHLW confirms that when companies need to refer to the content of a prior consultation they only need to provide the date and location of the prior consultation. If a company requests, quarantine stations will stamp the instructions received at prior consultations with the date and name of the quarantine station.
- c. As a general rule, information contained on food import notification documents submitted to quarantine stations is not open to the public in accordance with the Act on Access to Information Held by Administrative Organs. MHLW confirms that quarantine stations explain to importers the purpose for requiring the information. Quarantine stations require the minimum level of information necessary from a point of view of food sanitation, and MHLW works to ensure consistent enforcement among quarantine stations. MHLW confirms that it does not require an exact and comprehensive disclosure of all ingredients.
- d. Most vitamin-based nutritional supplements fall under the 2106.90.295 HS code with a tariff of 12.5 percent, and many other nutritional supplements such as mineral nutrients fall under the 2106.90.299 HS code with a tariff rate of 15 percent. 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 those on nutritional supplements containing the same ingredients as medicaments in WTO negotiations comprehensively. The Government of Japan will continue to discuss this issue with the Government of the United States.

G. Cosmetics and Quasi-Drugs

1. Quasi-Drugs:

- a. With regard to publishing the list of active ingredients (level and product categories) in medicated cosmetics, MHLW will publish the list after reviewing the information provided by the industry, including U.S. industry, by the end of 2008.
- b. In March 2008, MHLW published a revised list of quasi-drug additives (Evaluation and Licensing Division Notification Number 0327004), which is available on MHLW's web site. MHLW will continue to exchange opinions concerning quasi-drug regulations, including the evaluation of additives in quasi-drug application, with industry, including U.S. industry.

- c. When industry, including U.S. industry, makes proposals of additional product standards, MHLW will review them carefully.
- 2. Advertising and Labeling:
 - a. MHLW continues to exchange opinions on the representation of the effectiveness of cosmetics, including that related to the expansion of the effectiveness of cosmetics, with relevant parties including U.S. industry.
 - b. MHLW will continue to exchange views on the acceptability under the existing scopes of the claim developed by industry on reducing the appearance of fine lines due to dryness. When a conclusion is reached, MHLW will communicate the results to industry and local authorities in a timely manner.
 - c. MHLW will continue to exchange views with industry, including U.S. industry, on developing industry self-standards that would allow for numerical claims.
- 3. Other Transparency and Regulatory Issues:
 - a. MHLW will continue to work with industry, including U.S. industry, to exchange views on and to increase the transparency of the Local Advertisement Controllers' Meetings (*Rokushakyo*) by offering interested industry associations an opportunity to exchange views, e.g. at the end of meetings or at industry-sponsored events on the margins of the meetings.
 - b. In April 2008, MHLW implemented a revised standard for sanitary pads after taking opinions and requests from related parties, including U.S. industry, into consideration.
 - c. MHLW will work with industry, including U.S. industry, to devise ways to streamline the import process of cosmetics by the end of 2009.
 - d. To the extent possible within resource constraints, MHLW will continue to improve its website in terms of publishing regulations and notifications in a timely manner.

IV. FINANCIAL SERVICES

- A. **Overview:** Both governments agree that competitive financial and capital markets are a key element contributing to sustained economic growth, efficient capital allocation, job creation, and innovation. The Financial Services Agency (FSA) released its "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets" on December 21, 2007, and the United States welcomes initial measures taken under the

Plan, including the enactment of the Bill for Amendment of the Financial Instruments and Exchange Act, etc. Additionally, in April 2008, the Cabinet Office's Urban Renewal Headquarters released its "Plan to Enhance Japan's Role as an International Financial Center" including the establishment of "International Financial Center Forum" whose role is to implement measures laid out in the Cabinet Office's Plan. 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. Credit Bureaus: The revised Money Lending Business Law calls for the expansion of credit information use and mandatory use of lenders' exchanges by consumer finance companies. Through lenders' exchanges of various types of consumer finance companies, the FSA is working to require the availability of full-file credit information in order for firms to price risk and promote sound credit underwriting on a rigorous, scientific basis as a means of consumer protection and financial system stability. In reviewing the functions of the Credit Bureau System, including financial institutions such as banks and consumer credit companies, firstly, the FSA will monitor developments in the problem of multiple debts.
2. Firewalls: Regarding firewalls regulations between banks and securities firms, the FSA will remove the ban on concurrent posts and ease restrictions on the sharing of undisclosed corporate customer information, while demanding that financial institutions put in place a system for controlling conflicts of interest. This was outlined in the Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets, which was published at the end of last year following discussions at the Financial System Council and hearings with market players, including foreign financial institutions. The FSA submitted a related bill to the Diet in March 2008 and the bill was enacted in June 2008. The detailed regulations will be clarified through the establishment of Cabinet Orders and Cabinet Office Ordinances. In implementing this plan, the FSA will continue to make efforts to promote dialogues with market players, including foreign financial institutions regarding firewall regulations.
3. Regulation of Financial Conglomerates: In connection with regulations that relate to the management structure and the sharing of information between group companies of a financial conglomerate, the FSA announced the "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets" in December 2007. This plan encompasses several measures aimed at revamping the so-called "firewall regulation," which includes the elimination of restrictions on the assumption of multiple positions by executive officers or other employees within a group, and the easing of restrictions on the sharing of undisclosed customer information between banking and securities businesses. In designing the above-mentioned plan, FSA has taken care to consult with various interested parties including foreign financial firms, and will continue to do so in revising the

existing guidelines for the supervision of financial conglomerates and the implementation thereof.

4. Defined Contribution Pensions:

- a. The Government of Japan recognizes the importance of the defined contribution pension system in terms of securing income for the elderly, promoting labor mobility, investment education, a renewed emphasis on retirement planning.
- b. The Ministry of Health, Labour and Welfare (MHLW) Corporate Pension Study Group examined the current corporate pension system, and made recommendations for improving defined contribution pensions in the July 2007 report titled “Results of Verification of the Situation regarding the Implementation of Corporate Pension Schemes,” including: tax deductible contribution limits, allowing employee contributions to corporate-type defined contribution pensions; consideration of present limits on contribution; consideration of conditions for early withdrawal; concerning possible participation by government employees in a defined contribution program; and provisions for investment advice.
- c. An ad hoc member and private sector members of the Council on Economic and Fiscal Policy proposed reforms of the defined contribution pension system, calling for the following improvements: allowing employee contributions; expanding eligibility criteria, including new government employees, housewives, and workers whose firms do not have corporate pension plans; improving the portability of the defined contribution system; easing restrictions on the upper age limit for participation, and the period of participation; and consideration of the tax treatment of the defined contribution pension system. Furthermore, on June 10, 2008, the Council on Economic and Fiscal Policy released “Strategies of Economic Growth,” which suggests that employee contributions should be evaluated by the end of 2008.
- d. An amendment bill to centralize the employee pension system, submitted in the ordinary Diet session 2007, incorporates a proposal to relax regulations on early withdrawal from the personal type of defined contribution pension, etc., in association with the amendment of the Defined Contribution Pension Law and the proposal is under deliberation.
- e. MHLW, taking into due consideration progress in the enforcement of the various systems and regulations put into place so far, will continue its efforts to improve the defined contribution pension system, in consultation with interested parties, on the tax treatment issues.

5. Harmonize the Regulatory Framework for Investment Advisory Services and

Investment Trusts: Under the Financial Instruments and Exchange Act (FIEA), “Investment Advisory Relevant Businesses,” “Discretionary Investment Businesses” and “Investment Trust Management Businesses” are classified as financial instruments firms and basically the same rules are applied thereto, although different registration requirements apply depending on the business. Also, entities conducting investment management business have been brought within the FSA’s jurisdiction by way of restructuring the authorities’ jurisdiction. Prior to their reallocation to the FIEA, the Japan Securities Investment Advisers Association and the Investment Trust Association were self-regulatory organizations based on different laws. Under FIEA both organizations are positioned within the Financial Instruments Firms Association, and are regarded as self-regulatory organizations under same law, but whether they will be consolidated into a single association is still up to individual industries’ constituents.

6. 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,” executed in September 2007. The merger and termination of investment trusts, including advance redemption, is allowed under the "Act on Investment Trusts and Investment Corporations," on the condition that the procedure for the petition of objection is “gone through,” such as gaining approval of at least half of all beneficiaries and two-thirds of all voting rights and the right of opposing beneficiary to claim the purchase of beneficial right by fiduciary, which is created considering the material impacts on the beneficiary’s right.
7. Materiality Standard in Net Asset Value (NAV) Calculations: In response to current “materiality” standards, many investment companies have already established their own benchmarks; whether an investment company establishes the “materiality” standards is ultimately up to individual companies. On the other hand, there are various causes for misinformation in the calculation of base price, and practitioners in the Investment Trusts Association, Japan are now considering the ideal method for “materiality” standards, to consider the relation between the “materiality” standard and law including the investment company’s professional due care and duty of loyalty.
8. Institutional Investor Disclosure Rules for Large Shareholdings: The Large Shareholdings Disclosure Rules for Institutional Investors were revised in 2006 and the new rules went into effect in January 2007. The FSA has been continuously monitoring market practices regarding large-shareholding transactions since then and will continuously monitor the situation in the future in consultation with relevant parties.
9. Global Custody: The global custody business is prescribed in the FIEA, the Act on Transfer of Bonds, the Banking Law as follows:

- a. A custody and settlement of securities shall be conducted only by financial instrument firms registered on the Prime Minister pursuant to the Financial Instruments and Exchange Act. In the case that the securities have not been issued, a settlement of the securities can be conducted by people who have been designated by the Prime Minister, the Minister of Justice and the Minister of Finance pursuant to the Act on Transfer of Bonds and the like.
- b. There are no particular regulations regarding the custody businesses in the case of delivering or receiving the interests from the securities, lending the securities, and exercising the attached shareholder's rights.
- c. Under the present system, a bank (including a branch office of foreign bank) may not conduct custody and settlement of securities, in the case of delivering or receiving the interests from the securities, lending the securities, and exercising the attached shareholder's rights on behalf of foreign banks.

Moreover, the introduction of a framework for agency and intermediary operations by banks on behalf of foreign banks (within the same group) is included in the bill for amendment of the Financial Instruments and Exchange Act, etc which was passed by the Diet in June 2008. Based on these provisions, the FSA and the Government of United States have discussed the regulatory framework of the global custody business. The FSA will continue to make efforts to have dialogues with relevant parties to share the understanding on the regulations of Japan.

C. **Transparency**

1. No-Action Letters and General Inquiries Regarding the Interpretation of Laws and Regulations: The FSA amended its detailed regulations regarding the no-action letter system in July 2007. The FSA is working to aggressively publicize the revised no-action letter system by such means as announcing it at a press conference and publishing information thereon in the FSA's public relations brochure. Following the changes made to the no-action letter system by the FSA in July 2007, two no-action letters have been processed with an average response time of 16 days. Moreover, the FSA has introduced the program for General Inquiries Regarding Interpretation of Laws and Regulations, which will complement the no-action letter system. Since its introduction in April 2005, the FSA has responded to one inquiry in 2007 by way of this program. The FSA will continue its efforts to enhance use of the no-action letter system and the program for General Inquiries Regarding Interpretation of Laws and Regulations.
2. Transparency in the Inspections Process: Both the FSA (Inspection Bureau) and the Executive Bureau of Securities and Exchange Surveillance Commission (SESCEB) have taken measures to enhance the transparency of the inspection

process. The FSA published the “Financial Inspection Basic Guidelines”, the “Inspection Manuals”, and further generated the “Basic Policy and Plan for Financial Inspections,” the “Financial Inspection Instruction Samples,” and the “Opinion Submittal Samples.” Similarly, the SESCEB published the “Basic Guideline for Inspection of Financial Instruments Firms” and the “Inspection Manuals for Financial Instruments Firms,” in addition to releasing the “Basic Policy and Plan for Inspection of Financial Instruments Firms” annually and quarterly updates to the “Main Findings in the Inspection of Financial Instruments Firms.”

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

By the same token, financial instruments firms (FIFs) being inspected by the SESCEB are given an opportunity to use the “on-site inspection monitoring” system, which enables the FIF to engage in a direct dialogue with senior officials of the SESCEB back office without the presence of inspectors while the inspection is still in process. The FIF can also express its views to the SESC back office in a written form by using the “off-site inspection monitoring” system within a month after the conclusion of the inspection. Furthermore, the “opinion submission system” allows the FIF to submit its opinions to the SESCEB back office in case it cannot agree with the inspectors’ findings even after thorough discussions.

The FSA and the SESCEB have been making improvements in system arrangements including those mentioned above in order to secure transparency of the inspection process, and will continue to manage the system properly in the context of promoting better regulation. The FSA continues to have opportunities for exchanging views with foreign financial institutions and financial sector industries’ associations in a variety of ways and at various levels, recognizing that the inspection process is a serious concern for institutions and the market. The SESCEB also continues to have opportunities for exchanging opinions with domestic as well as foreign FIFs and their industrial associations to discuss issues surrounding the developments of financial markets and/or identified in on-site inspections. The FSA and the SESCEB will continue to have open

communications with financial sector industries as well as their associations.

3. Ensuring Transparency in Implementation of the “Plan for Strengthening the Competitiveness of Japan’s Financial and Capital Markets”: The FSA utilized the information and opinions provided by way of dialogue with market players, including foreign financial firms, in the process of drafting the “Plan for Strengthening the Competitiveness of Japan’s Financial and Capital Markets” and related bills. The FSA will continue to make efforts to engage in dialogue with market players in order for the aims of the plan to be fulfilled.

V. COMPETITION POLICY

A. Improving Antimonopoly Compliance and Deterrence

1. Strengthening Antimonopoly Act Enforcement and Deterrence:

- a. The Government of Japan submitted the Antimonopoly Act (AMA) Amendment Bill to the Diet in March 2008, which includes a 50 percent increase in the surcharge rate for enterprises that played a leading role in an unreasonable restraint of trade (e.g. an increase of the surcharge from 10 percent up to 15 percent of sales for large manufacturing enterprises that play a leading role in the conspiracy), as well as the extension of the statute of limitations for both cease and desist orders and surcharge payment orders from the current three years to five years.
- b. The AMA Amendment Bill maintains the current system allowing the imposition of both criminal penalties and administrative measures on enterprises that engage in cartel and bid-rigging activities.

2. Utilizing the Leniency Program:

- a. The Japan Fair Trade Commission (JFTC) has promoted active use of the leniency program by enterprises and has utilized the leniency program actively as follows. In Japan FY 2007, JFTC received 74 leniency applications, bringing the total number of leniency applications since the introduction of the leniency program to approximately 180. Among the cases where enterprises applied for leniency since January 2006, JFTC took legal measures in 22 cases, including a February 2008 action against an international cartel concerning marine hose.
- b. The AMA Amendment Bill allows two or more enterprises within the same company group, upon certain conditions, to jointly file a leniency application and be assigned the same order of priority.
- c. The AMA Amendment Bill also increases the number of enterprises that are allowed to apply to the leniency program from the current maximum of three to five, with the third through fifth applicants receiving a 30 percent

reduction in the surcharge. However, in order to ensure incentives for enterprises to apply to the leniency program as early as possible before JFTC search and seizures, application after the initiation of an investigation is limited to no more than three enterprises, and there will continue to be a significant difference between the benefits received by the first applicant (complete immunity from surcharge) compared to subsequent applicants.

3. Increasing Deterrence through Criminal Enforcement:

- a. JFTC will continue to give high priority to investigating cases suspected of involving criminal violation of the AMA and to filing criminal accusations against companies and individuals engaging in vicious and serious cartel cases violating the AMA, based on “The Fair Trade Commission’s Policy on Criminal Accusation and Compulsory Investigation of Criminal Cases Regarding Antimonopoly Violations.”
- b. The Public Prosecutors Office will continue to appropriately deal with cases where the JFTC files a criminal accusation.

4. Minimizing Unintended Deterrence of Procompetitive Unilateral Conduct:

- a. The AMA Amendment Bill would subject enterprises that engage in the exclusionary type of private monopolization, abuse of superior bargaining position, and certain types of concerted refusal to trade, discriminatory pricing, unjust low price sales and resale price restrictions, to surcharges. JFTC considers it important to ensure transparency and predictability of law enforcement in order to avoid chilling legitimate business conduct caused by the expansion of the scope of conduct subject to surcharges. From this perspective, the AMA Amendment Bill clarifies the specific requirements for finding an AMA violation for concerted refusal to trade, discriminatory pricing, unjust low price sales, resale price restriction and abuse of superior bargaining position that will be subject to surcharges.
- b. In addition, before the amendments come into effect, JFTC will issue guidelines to clarify the conduct that will constitute the exclusionary type of private monopolization that will be subject to surcharges. JFTC will publish a draft of the guidelines and solicit and consider public comments before finalizing the guidelines.

5. Reviewing AMA Exemptions:

- a. On December 5, 2007, JFTC released the report of its Study Group on Regulation and Competition Policy, which found that it was difficult to provide a good rationale for the continuation of the AMA exemption in the international aviation sector.

- b. On March 25, 2008, the Government of Japan decided that the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) would start to review the AMA exemption system for agreements by air carriers in the international aviation sector within 2008.
 - c. The International Maritime Transport Sub-committee, a special group under the Maritime Affairs Section of the Council for Transport Policy, which is a ministerial advisory body for the MLIT Minister, considered in 2007 whether the antimonopoly exemption for international shipping activities continued to be necessary. After careful consideration, the Council recommended in December 2007 that further consideration be given to this issue from the viewpoint of ensuring a competitive international shipping market while ensuring stable and reliable maritime transport. Accordingly, MLIT intends to make further studies on this issue from the following four points of view which were described in the above recommendation:
 - (1) the antimonopoly policies taken by other nations and the impact of those policies on the Japanese shipping industry,
 - (2) the development of the international shipping market including the emergence of large shipping companies,
 - (3) whether the agreements among shipping companies are working for stable supply of the shipping service, and
 - (4) the impact on the Japanese economy.
6. Providing Guidance on AMA Compliance:
- a. On September 28, 2007, JFTC issued its Guidelines for the Use of Intellectual Property under the AMA.
 - b. As mentioned above, before the AMA amendments come into effect JFTC intends to issues guidelines on the types of conduct that may fall within the exclusionary type of private monopolization.
7. Improving Pre-merger Notification Procedures: The AMA Amendment Bill provides for prior notification of share acquisitions by corporations in the same way as for other types of business combination such as mergers. The AMA Amendment Bill also revises the notification thresholds for business combinations, including by providing that, in principle, the notification threshold will be based on the total amount of domestic turnover of a corporate group. These revisions are consistent with the International Competition Network's "Recommended Practices for Merger Notification Procedures" and OECD's "Recommendation of the Council on Merger Review."

8. Strengthening JFTC Staff and Resources: JFTC has steadily increased its staff and budget. The total number of its staff is expected to reach 795 as of March 31, 2009, an increase of 30 staff compared to the end of March 2008. 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 Fairness and Transparency of JFTC Administrative and Investigatory Procedures

1. Reviewing Current Hearing Examination System: The Government of Japan is committed to promoting public confidence and transparency of the JFTC hearing examination system. In this regard:
 - a. A supplementary provision of the AMA Amendment Bill provides that the Government of Japan shall review the current ex-post hearing examination system in its entirety and carry out consideration within FY 2008 from the perspective of ensuring that respondents in JFTC investigatory and enforcement procedures are afforded procedural fairness consistent with fulfillment of the purposes of the AMA. The views of all interested parties submitted, including those from the foreign business and legal communities, will be considered. Based on the results of that consideration, the Government of Japan will take appropriate measures as soon as is practicable.
 - b. The report of the Expert Committee on FDI Promotion, which was submitted to the Council on Economic and Fiscal Policy on May 20, 2008, called for strong measures by the Government of Japan to “dramatically increase” foreign direct investment. That report recommended, among others, measures to review in its entirety the JFTC hearing examination system from the viewpoint of neutrality and fairness and examine what the due process of AMA investigation procedures should be, taking into account such factors as harmonization with international standards, consistency with other systems in Japan, and differences in the judicial systems in Japan and other countries.
2. Enhancing Public Confidence and Transparency of JFTC Procedures: JFTC is committed to promoting public confidence and transparency of JFTC investigatory and hearing procedures. In this regard:
 - a. Although JFTC has undertaken to provide expected recipients of cease and desist orders or surcharge payment orders with approximately two weeks in principle from the time that JFTC notifies them in writing of the contents of expected cease and desist orders or surcharge payment orders to review the evidence JFTC intends to use against them and to present their opinion and submit evidence to JFTC before JFTC will make a final

determination, JFTC sets the above prior notice and response period appropriately on a case by case basis, taking into account factors such as the time needed for prior explanation. Based on the JFTC's Rule on Administrative Investigation, which stipulates that the period can be extended by JFTC's authority or at the request of the expected recipients, JFTC has extended and will continue to extend the prior notice and response period when there is a justifiable reason.

- b. Currently, four out of seven JFTC hearing examiners are legal professionals who are not career JFTC officials, and JFTC has ensured that the panel of hearing examiners for each public hearing includes at least one such legal professional. JFTC will revise its Rules on Hearing to stipulate that the panel of hearing examiners for each public hearing shall include at least one such legal professional.
 - c. The AMA provides that any person who has performed duties of an investigator of the said case or who has otherwise been involved in the examination of the said case shall not be designated as a hearing examiner for the said case. In addition to this provision, JFTC will revise its Rules on Hearing to stipulate provisions to prevent any person who has a conflict of interest in the matter that may obstruct a fair hearing procedure from acting as a hearing examiner in a particular case, with a view to further promoting fairness and transparency of hearing procedures.
 - d. JFTC will stipulate in its Rules on Administrative Investigation procedures concerning issuance of warning, including procedures that ensure fairness in the issuance of warnings and the publication of the names of warning recipients.
3. Confidentiality of Communications between Attorneys and Clients: JFTC will treat documents containing communications between an attorney and his or her client that relate to the provision of legal advice sought by the client appropriately in accordance with Article 100 of the National Public Service Act and, if applicable, Article 39 of the AMA if such documents include confidential information protected by the said provisions, considering that such documents are, in principle, intended to be confidential between an attorney and his or her client.

C. **Addressing Bid Rigging**

- 1. Strengthening Penalties against Bid Rigging:
 - a. The Government of Japan, with the view to preventing improper activity including bid rigging, amended the Budget, Settlement of Account and Accounting Regulations and the Cabinet Order of Local Government Autonomy Law in February 2008. The revisions include the extension of the maximum period that each central government and local government

procuring entity can ban persons who it has found to have engaged in bid rigging activities or other improper activities from taking part in open and competitive bidding, to three years (from the previous maximum ban of two years) on contracts awarded after March 2008.

- b. MLIT increased, in September 2007, the minimum suspension period to 15 months (from 12 months) for a company that is criminally accused or whose executive or employee is accused or arrested in connection with a serious AMA violation on MLIT-contracted public works projects, where such company was a ringleader of the bid rigging conspiracy or engaged in illegal bid rigging activity despite submitting a written pledge not to violate the AMA.

2. Preventing Conflicts of Interests:

- a. The bill to amend the National Public Service Act and relevant laws, which included provisions regarding reemployment of retiring government officials, passed the Diet in June 2007. The amendments restrict government officials from seeking jobs and brokering employment opportunities, and retired officials from contacting incumbent officials, and, effective December 27, 2007, provide criminal penalties for violations of those restrictions.
- b. In addition, the Cabinet submitted a bill to the Diet in May 2007 to amend the Local Public Service Law. The bill would restrain retired officials from contacting incumbent officials, and would provide criminal penalties against offenders.

3. Preventing Government-Assisted Bid Rigging:

- a. Regarding the demand for improvement measures to procuring entities issued in accordance with the Act on Elimination and Prevention of Involvement in Bid Rigging, etc. and Punishments for Acts by Employees that Harm Fairness of Bidding, etc., JFTC will continue to make public the content of its demand for improvement measures to procuring entities, the outline of the procuring entities' involvement acts in bid rigging, etc., and relevant articles. Moreover, this Act requires that the procuring entities subject to the demand by JFTC shall conduct necessary investigation, and publicize the results of the investigation as well as the content of the improvement measures taken.
- b. Although it is up to each procuring entity's discretion to take disciplinary sanction against officials who are involved in bid rigging activities, etc., and to make public the sanctions taken, the abovementioned Act requires procuring entities to conduct investigations on whether or not the official's acts warrant disciplinary sanction and to publicize the result of the

investigation. Thus, procuring entities are required to take strict action against officials who are involved in bid rigging, etc.

4. Expanding Administrative Leniency: Based on the Act for Promoting Proper Tendering and Contracting for Public Works, MLIT, MIC and MOF conducted a survey on the efforts, as of September 1, 2007, of public procuring entities to implement proper tendering and contracting procedures for public works, and published the results on December 19, 2007. According to the survey results, 10 out of 18 central government entities adopted an Administrative Leniency program that reduces the period of suspension from bidding for companies admitted into JFTC's Leniency program. According to a later survey, the Cabinet Office (partially), MOJ, MOF, MEXT, MHLW, MAFF, MLIT, MOD, the Board of Audit, and the Supreme Court have adopted the above program. In addition, on June 20, 2008, the Ministry of the Environment adopted the above program, bringing the total number of central government entities that have adopted an Administrative Leniency program to 11.
5. Improving Procurement Practices:
 - a. According to the results of the above MLIT, MIC and MOF survey on efforts by public procuring entities to implement proper tendering and contracting procedures for public works, about 80 percent of the central government entities have adopted the Overall Greatest Value Method for public works. MLIT conducted about 90 percent of its public works procurement (on a value basis) using the Overall Greatest Value Method in FY2006.
 - (1) MIC and MLIT requested local governments in March 2008 to expand use of the Overall Greatest Value Method for public works. In addition, the Government of Japan revised the Cabinet Order for the Local Autonomy Law in February 2008, effective in March 2008, in order to simplify the procedures for using the Overall Greatest Value Method so that the method could be widely introduced and expanded in public works undertaken by the local governments. As of September 1, 2007, 100 percent of prefectures and designated cities, and 24.3 percent of municipalities had adopted the Overall Greatest Value Method for public works.
 - (2) The Government of Japan will continue to promote the introduction of the Overall Greatest Value Method by central and local government procuring entities with the purpose of increasing public works procurements that use that method, including through opportunities such as the "Meeting of Related Governmental Ministries Regarding Promoting Proper Public Procurement."
 - b. MIC and MLIT continue to encourage local governments to further promote proper tendering and contracting for public works by local

governments, including by implementing open and competitive bidding systems and installing electronic bidding systems. According to the results of the above survey, 55 percent of local governments have adopted open and competitive bidding and 21 percent have installed electronic bidding systems as of September 1, 2007.

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

VI. COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

A. Promoting Efficient Restructuring and Shareholder Value

1. Facilitating the Use of Modern Merger Techniques:

- a. As a result of provisions of the 2005 Companies Act relating to “flexibility of merger consideration” that came into effect in May 2007, foreign companies were permitted to obtain all of the shares of Japanese companies through triangular mergers. These provisions were enacted to establish the triangular merger system as an effective tool for active corporate restructuring and the promotion of FDI to Japan.
- b. On May 20, 2008, the Expert Committee on FDI Promotion submitted its report and recommendations to the Council on Economic and Fiscal Policy (CEFP). That report called for strong measures by the Government of Japan to “dramatically increase” foreign direct investment. In particular, the report recommended measures to encourage more cross-border M&A activities, including an analysis of why there has been only one transaction where the triangular merger technique was used and a review of the tax deferral rules and other aspects of the legal system applicable to M&A, including triangular mergers, with the view to facilitating cross-border M&A activities.

2. Protecting Shareholder Interests in Anti-Takeover Measures:

- a. The Economic Growth Strategy Report issued on June 10, 2008 states that the Government of Japan will set up a fair and transparent M&A climate

including through identification and clarification by the Ministry of Economy, Trade and Industry (METI), the Ministry of Justice (MOJ), and the Financial Services Agency (FSA) by summer of 2008 of conditions for the introduction and invocation of defensive measures. The Basic Policies 2008 decided by the Cabinet on June 27, 2008, incorporates the abovementioned content of the Economic Growth Strategy Report.

- b. METI and MOJ jointly formulated “Takeover Defense Guidelines for Protecting and Enhancing Corporate Value and the Interests of Shareholders as a Whole” on May 27, 2005. The Guidelines set the principle of the reflection of shareholders’ will as one of the most important principles, and stipulate that when takeover defense measures are introduced, such measures should reflect the reasonable will of the shareholders and should not be abused for the purpose of the entrenchment of current management
- c. Corporate Values Study Group:
 - (1) METI has tasked the Corporate Values Study Group (CVSG) with reviewing takeover defensive measures, including cross-shareholding arrangements, in light of the actual practice of Japanese companies and recent court decisions, with the aim of issuing a report that will clarify the guidelines for the appropriate use and implementation of takeover defensive measures consistent with their proper objective of promoting corporate value and the interests of shareholders rather than protecting management.
 - (2) The CVSG, in accordance with the Economic Growth Strategy Report, concluded in its report issued on June 30, 2008, that hostile takeovers can have positive benefits both for shareholders and the target company by, for example, instilling discipline on management and promoting the interests of shareholders. The CVSG also concluded that takeover defensive measures, in principle, should not be invoked, since invocation of such measures deprives shareholders of a chance to accept an offer if they so choose. The CVSG also determined that management has an obligation to make responsible judgments about the attractiveness of takeover bids from the standpoint of the interests of shareholders, as well as about whether the adoption or invocation of defensive measures will increase corporate value and further shareholder interests.
- d. In November 2007, the Tokyo Stock Exchange (TSE) issued its Code of Corporate Conduct to include the following requirements regarding the introduction of takeover defensive measures by listed companies:

- (1) The listed company shall make necessary and sufficient timely disclosure concerning takeover defense measures;
- (2) Conditions of implementation and abolishment of takeover defense measures shall not depend on arbitrary decisions by the management;
- (3) Takeover defense measures shall not include factors which may cause extremely unstable price formation of a stock or any other factors which may cause unpredictable damage to investors;
- (4) Takeover defense measures shall give consideration to shareholders' rights and their exercise.

Pursuant to FSA's "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets," TSE plans to revise its Corporate Code of Conduct within FY 2008 to further improve the efficacy of its Corporate Code of Conduct from the perspective of the protection of shareholder rights.

- e. The amended Tender Offer System, which came into effect in December 2006, requires a company that has received a tender offer bid (TOB) to publish a "position statement report." The position statement report must include, not only affirmative, negative, or other opinions on the TOB, but also the concrete decision-making process used by the company in reaching its position, as well as other matters. The company is also required to disclose measures that the company took to avoid potential conflicts of interests on directors.
- f. The Government of Japan expects that potential conflicts of interests on boards of directors will be eliminated through ensuring compliance with the above rules under the Financial Instruments and Exchange Act. It will continuously monitor the effectiveness of the new system.

B. Strengthening Good Corporate Governance: The Government of Japan recognizes the importance of strong and effective corporate governance mechanisms in preventing corporate misconduct and improving corporate competitiveness and earnings strength, and is committed to taking measures to strengthen corporate governance in Japan.

1. For instance, on December 21, 2007, based on a decision of the Cabinet, FSA formulated and published the "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets." That Plan calls for broad-reaching measures to strengthen corporate governance, including (1) review of implementation of the internal control reporting system and possible revision or clarification of the standards for internal corporate controls as a result of the review; (2) encouragement of stock exchange efforts to strengthen corporate

governance, including through the enhancement of TSE's Code of Corporate Conduct; and (3) broad examination of the current legal system in this area, with a view to identifying possible legislative and/or other measures necessary to strengthen corporate governance of listed companies. FSA, working with other relevant agencies, will conduct this broad review in a timely manner, and will solicit views from interested parties, including the foreign business community.

2. Encouraging Active and Appropriate Proxy Voting:

- a. TSE revised its listing rules in November 2007 to require listed companies to make efforts to send shareholders the notice of the shareholders meeting, including reference materials for exercising voting rights at the shareholders meeting, earlier than the two weeks in advance of the shareholders meeting required by the Companies Act in order to make it easier for shareholders to exercise their voting rights at shareholder's meetings. FSA supports these and other efforts by the exchanges to promote the smooth execution of voting rights.
- b. The Ministry of Health, Labour and Welfare (MHLW) has determined that, according to the Employees' Pension Insurance Law and the Defined Benefit Corporate Pension Law, pension fund managers and other trustees of pension funds have a fiduciary responsibility that includes an obligation to exercise voting rights for the benefit and solely in the interest of the beneficiary. MHLW will spread awareness of its position on the above fiduciary responsibility of trustees of pension funds, including through the review of its 1997 and 2002 guidelines pertaining to the role and obligations of trustees of pension funds, and will keep a close watch on the views of pension fund managers, etc., in this regard.
- c. The Government of Japan confirms that investment managers are required by the Financial Instruments and Exchange Act and the Act on Investment Trusts and Investment Corporations to direct the execution of voting rights regarding securities held as investment trust assets. Moreover, the Investment Trusts Association has issued operation rules for the execution of voting rights of investment managers that require that investment managers develop and disclose their standards for the execution of voting rights, and execute said rights based on that standard.
- d. FSA has determined that investment managers operating under the Financial Instruments and Exchange Act have a fiduciary duty of loyalty and professional due care to exercise proxy voting rights solely for the interest of beneficiaries, and are liable for damages suffered by such beneficiaries caused by a breach of this fiduciary duty.

3. Foster Protection of Shareholder Interests through Independent Directors:

- a. With respect to the definition of “outside” directors, the Government of Japan has been continuously reviewing the adequacy of the current definition and other related issues, considering various factors such as volume of human resources in Japan and that the Companies Act leaves the election of outside directors to the decision of the shareholders under strict disclosure rules.
- b. From the viewpoint of improving corporate governance of listed companies, FSA, based on its “Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets,” will redouble its encouragement of each stock exchange, including TSE, to make utmost efforts to strengthen the corporate governance of their listed companies, such as requiring listed companies to prepare corporate governance reports which contain information on any relationship between an outside director and the listed company, or its parent, subsidiaries, or major shareholders, and publicly disclosing the contents of those reports. TSE published its analysis of the current situation of corporate governance of listed companies based on corporate governance reports.
- c. In March 2008, TSE issued its three-year Medium-term Management Plan in which it stated that its basic strategy is to “facilitate enhanced corporate governance of listed companies.” This was followed, on May 27, 2008, by TSE’s announcement of its basic policies for Listing System Improvement 2008, which indicates that TSE will focus its efforts in FY2008 on two themes: improving conditions to enhance the corporate governance of listed companies, and following-up on the Comprehensive Improvement Program for the Listing System 2007.
 - (1) TSE considers the enhancement of the corporate governance of listed companies to be a key factor for the sound development of the Japanese securities market and will place the highest priority on the development of measures to address corporate-governance-related issues in FY 2008, including improvement of the Corporate Code of Conduct in this regard. Specific issues to be addressed include issuance of new shares causing substantial dilution to existing shareholders, non-transparent third party placements of new shares, reverse stock splits that significantly harm shareholder rights, potential problems regarding the independence of directors and auditors, and the introduction of takeover defense measures in a problematic manner.
 - (2) TSE will, by the end of 2008, take inventory of the different issues presented regarding improvements of corporate governance, including by soliciting the views of foreign and domestic investors and other interested parties, and will develop a concrete plan of comprehensive measures that it will seek to implement.

4. Ensuring Sufficient Protection of Minority Shareholders:

- a. The Government of Japan is committed to creating vibrant financial markets in which investors can have confidence, including through improved fairness and transparency. In this regard, the Government of Japan will, as part of the implementation of FSA's "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets," consider the adequacy of existing laws and regulations in protecting the rights of all investors. The Government of Japan will encourage the stock exchanges to make self-regulation rules more effective to ensure that minority investors of listed companies are not unreasonably disadvantaged.
- b. In June 2007, JASDAQ issued a letter stating that listed companies that have a parent company elect outside directors and statutory auditors that have no affiliation with the parent company. TSE has also issued a letter to address its policy regarding listed companies that have controlling shareholders. In addition to reviewing the Corporate Code of Conduct, TSE will create a concrete plan for the protection of shareholder rights, especially those of minority shareholders, during FY 2008 as stated in its May 27, 2008 announcement of its basic policies for Listing System Improvement 2008, building on the recent diversification of methods to ensure the efficacy of listing rules.
- c. METI published the guideline on management buy-outs (MBOs) on September 4, 2007. METI will continue to monitor the effectiveness of those guidelines in ensuring that minority shareholder interests are sufficiently protected in MBOs and similar transactions.

C. Protecting Foreign Firms Legitimately Doing Business in Japan

1. Redomestication Procedures: In view of the needs of the foreign business and legal communities, MOJ has examined the legal issues involved in the adoption of a simple procedure that would permit a foreign company to convert into a Japanese corporation. MOJ is of the view that such a redomestication procedure involves quite complicated issues from the perspective of not only the Companies Act but also the overall legal system. MOJ will continue to examine if there is any feasible solution that may satisfy such needs with any input from the foreign business and legal communities as necessary.
2. Monitoring the Effects of Article 821: The Government of Japan will continue to watch closely the effects on foreign companies of Article 821 of the Companies Act and consider amendment of Article 821 if necessary to prevent adverse effects on the legitimate operation of foreign companies in Japan.

D. Achieving Legal System Reform

1. Permitting Professional Corporations and Branches: The Ministry of Justice (MOJ) and the Japan Federation of Bar Associations (Nichibenren) have established "A foreign lawyer institution study group" in order to investigate and make recommendations regarding necessary measures for the establishment of professional corporations by registered foreign lawyers in Japan with the goal of reaching a conclusion by the end of 2008.
2. Allowing *Bengoshi* to Associate Freely with International Legal Partnerships: MOJ will continue 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 FY2008, including by hearing the views of foreign law firms operating in Japan.
3. Promoting Arbitration and Other Alternative Dispute Resolution:
 - a. The Government of Japan confirms that *gaiben*, foreign lawyers and non-lawyer are permitted to act as neutrals in arbitration procedures under the Arbitration Act regardless of the governing law or matter in dispute.
 - b. The Government of Japan confirms that in ADR procedures other than arbitration, *gaiben*, foreign lawyers and non-lawyers whose services have been certified by the MOJ under the Act on the Promotion of Use of Alternative Dispute Resolution are able to act as neutrals in ADR procedures for services which have been certified.
 - c. The Government of Japan confirms that *gaiben* are also able to act as neutrals in ADR procedures within the scope of their authority, as well as in ADR procedures outside the scope of their authority on a case by case basis, regardless of whether or not they have been certified by MOJ for their ADR services.
 - d. 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.
 - e. MOJ will continue to research whether measures can appropriately be taken to provide greater legal certainty regarding the ability of *gaiben* to act as neutrals, or to represent parties, in all international ADR proceedings taking place in Japan.

VII. TRANSPARENCY

A. Public Input into Policy Development – Advisory Groups

1. The Government of Japan recognizes the view of the Government of the United

States that the transparency of and access to advisory groups should be enhanced through the establishment of stronger transparency standards governing these groups. Advisory groups are administered by Ministries and Agencies in accordance with their respective establishment laws and regulations, the Cabinet Decision of April 1999 regarding "Basic Plan for the Rationalization of Councils, etc." and other guidelines and regulations. In accordance with these laws and regulations, these groups, for example, in principle are to publish meeting minutes and endeavor to provide opportunities to hear opinions of interested parties. The Government of Japan notes the request of the Government of the United States that the Government of Japan will, by the end of calendar year 2008, undertake a comprehensive review of the practices of advisory groups under Japanese Ministries and Agencies to objectively assess compliance with the April 1999 Cabinet Decision. Furthermore, the Government of Japan and the Government of the United States will continue to exchange information on transparency best practices for advisory groups, study groups, and similar groups.

2. Lists of some of the advisory groups and their membership are electronically accessible through "e-Gov," a government portal website (<http://www.e-gov.go.jp>).
3. The Government of Japan will continue to promote the above-mentioned measures regarding transparency of and access to advisory groups.

B. Public Comments

1. 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. The APA requires Ministries and Agencies to set comment periods of at least 30 days in principle to provide meaningful opportunities for input from the public and to fully take comments into consideration before their draft orders/regulations are made final. The Ministry of Internal Affairs and Communications will furthermore encourage Ministries and Agencies to provide public comment periods longer than 30 days where possible as a best practice.
 - b. For meaningful implementation of the PCP, the Government of Japan regards it 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 encourage and promote better implementation of the procedure as necessary by maintaining close communications with relevant Ministries and Agencies.

2. The Government of Japan and the Government of the United States discussed the request by the Government of the United States that Japanese Ministries and Agencies make efforts to provide opportunities for public comments on draft legislation whenever possible.
- C. **Transparency in Regulation and Regulatory Enforcement:** The Government of Japan understands the importance of the private sector having sufficient information on regulations and ensuring 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 takes note of the request by the Government of the United States that the Government of Japan, before the end of calendar year 2008, solicit views and examine the need for the introduction of requirements of Japanese Ministries and Agencies to make generally-applicable interpretations of regulations available to the public. The Government of Japan will also promote the use of plain language when drafting regulations to prevent arbitrary and inconsistent interpretation.
- D. **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.
- E. **Foreign Translations of Japanese Laws:** On March 28, 2008, the Government of Japan, with due consideration to opinions of domestic and foreign experts, re-revised the Translation Development Program for FY2006-FY2008. The number of English translations of Japanese laws and regulations to be translated has increased by 100, and will now total approximately 300 translations under the program. Based on the program, the Government of Japan has produced approximately 120 English translations of laws and regulations as of the end of April 2008. 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. From FY2009, the Ministry of Justice will assume responsibility for the main part of this Program, including the establishment of a new web site.
- F. **Implementation of Rulemaking:** The Government of Japan will enforce 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. Each Ministry and Agency has made and will continue to make efforts to make clarifying documents, such as implementing guidelines or regulations, available as soon as possible after publication of final regulations.

VIII. OTHER GOVERNMENT PRACTICES

A. Bank Sales of Insurance

1. The Government of Japan fully liberalized the bank sales channel for insurance products on December 22, 2007. The FSA has found “no significant violations” of the measures to prevent harmful effects with regard to bank’s insurance sales practices, demonstrating that a robust bank sales channel is consistent with strong consumer protections. The ban on selling insurance products at banks had been gradually lifted since the year 2001 taking care to prevent harmful effects. During this process, based on the wide range of comments that were expressed through discussions with both domestic and foreign interested parties, the FSA amended the related cabinet ordinance to ensure greater protection for the consumer and this came into effect on the same day (on December 22, 2007). Moreover, even after the full liberalization, while confirming to monitor the insurance sales by banks and the like, the FSA will, if needed, revise measures to prevent its harmful effects after approximately another three years with respect to the consumers’ protection, convenience and benefits.
2. The Government of Japan deems it important that the rules governing bank sales ensure consumer protection and are implemented fairly, including in a manner that does not favor one product, sales method or services supplier over another.
3. Taking medium and small size financial institutions’ business into consideration, the FSA has relaxed the limitation of insurance solicitation by banks to customers and has carried the measures to relax the restriction separating the person in charge of business loan from one in charge of insurance soliciting business. The Government of Japan has taken an interim step to revise the 10 million yen limit on sales of third sector insurance products by medium and small size financial institutions to employees of small- and mid-size companies, a step welcomed by the Government of the United States.
4. 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 consumers, and solicited public comments on the draft amendments of the Cabinet and Ministerial Ordinances of Insurance Business Law as well as guideline for insurance companies supervision. During the process of monitoring insurance solicitation by banks and conducting further review, development, and/or implementation of market conduct rules, the FSA will ensure meaningful opportunities for and hold hearings with insurance companies (including foreign companies), banks, and other various relevant parties based on request.

B. Insurance Cooperatives

1. With regard to unregulated *kyosai*, an amendment to the Insurance Business Law (IBL), 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. 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. The amended IBL stipulates that FSA will review the SASTIP system within five years from the date of its enforcement (i.e., before April 2011). To conduct the review, the FSA will, as necessary, provide information on the review and meaningful opportunities for input from insurance companies, including foreign insurance companies, and other parties concerned.
2. With regard to regulated *kyosai*, the Government of Japan and the Government of the United States have discussed the view of the Government of the United States that the Government of Japan should 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 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. The Government of Japan and the United States Government will continue to discuss the relevant issues in the Regulatory Reform and Competition Policy Initiative.

C. **Policyholder Protection Corporation**

1. The amended Insurance Business Law, which came into effect on April 1, 2006, extended the period of the existence of the financial assistance by the government-funded resources in case of an insurance company bankruptcy in the Insurance Policyholder Protection Corporation (PPC) scheme. This amended law also stipulates that the system regarding PPC's financial resources will be reviewed within three years from April 1, 2006.
2. The Government of Japan and the Government of the United States discussed the United States' request that PPC is used as a last resort, including through a shift to a post-funding system to help ensure that a more efficient, sustainable safety net system is created when the current system is reviewed.
3. In implementing this review, the Financial Services Agency (FSA) and the related advisory groups convened by the Government of Japan will provide private sector interested parties, including foreign insurance companies, with information on reviews as well as meaningful and timely opportunities to express and exchange

views, on the deliberations of the related advisory groups to prepare for draft legislation.

D. Domestication of Foreign Insurance Operations

1. The Government of Japan and Government of the United States discussed the issue of branch conversion. The Government of Japan is aware of the following:
 - a. The Government of the United States' position is that the Government of Japan take the necessary measures so that foreign incorporated insurance companies operating branches in Japan that wish to transfer their businesses to a Japanese entity or another foreign insurance company can protect their policy holders, creditors, and maintain continuity of business through seamless process, which would include the elimination of a sales blackout rule for the transfer of portfolios between sound companies; and
 - b. The Government of the United States requests the Government of Japan to consider the issue in further detail, within the next year, and to undertake further consultations with the Government of the United States and industry, including foreign companies, to address the issue.
2. The Government of Japan's position is that the sales blackout rule in the portfolio and business transfer provision of the Japanese Insurance Business Law aims to protect consumers who newly enter contracts subject for transfer and clarify the scope of contract subjects for transfer.
3. Also, regarding (1) transfer to a Japan-incorporated entity, (2) the establishment of statutory disclosure, notice and deemed approval procedure with all creditors, and (3) allowing the transferee entity to assume all assets and liabilities of the transferring entity in transactions approved by FSA and creditors, the reorganization and realignment of insurance companies should also be based upon procedures of the Japanese company law.
4. There seems to be little significant legal support the permitting a "deemed license," since the verification of proof, that the transferee entity is able to provide the same conditions and transaction methods as it did before the transfer, is conducted in the same manner as the verification of the new license.
5. The Government of Japan would like foreign incorporated insurance companies to consult with it individually, should they face this particular problem regarding the transfer to a Japan-incorporated entity.

E. Consular Issues

1. Re-entry Permit System: The Revised Three-Year Plan for the Promotion of Regulatory Reform (approved in the Cabinet meeting on March 25, 2008) called

for a review of the re-entry permit system that will take into consideration such factors as the treatment of highly-skilled foreign nationals in other countries and the specific characteristics of each status of residence, on the premise that a new system for residence management will be established. The review of the re-entry permit system is scheduled to be conducted at the very latest when new laws and regulations come into effect mandating the establishment of a new system for residence management. (The bills of relevant laws and regulations are to be submitted to the ordinary session of the Diet in 2009 at the latest.)

2. Designated Activities Visas for Foreign Domestic Employees:

- a. The Government of Japan recognizes and appreciates that the Government of the United States has a strong interest in reviewing the requirements for the issuance of designated activities visas for foreign domestic employees, because of the concerns of the Government of the United States and many foreign investors in Japan that regulations regarding entry into Japan of foreign domestic employees affect businesses' ability to recruit executive staff from overseas.
- b. A foreign national who is an employer of a domestic employee must meet specific requirements in addition to being the head of an office or being in an equivalent position. In order to decide whether or not he/she corresponds to such criteria mentioned above, such factors as the size of the office to which the foreign national concerned belongs, the number of subordinates and the employer's authority within the office, and his/her personal circumstances are individually taken into consideration.
- c. Provisions concerning the entry of foreign domestic employees are established based on a policy decision of the Government of Japan on the acceptance of foreign workers. There are some cases in which the Government of Japan has permitted the entry of foreign domestic employees even when such cases did not fall within the scope of the existing provisions in cases where, taking into consideration individual circumstances, special consideration was required on humanitarian grounds.
- d. The Government of Japan welcomes further discussion with the Government of the United States and interested parties about the impact of these regulations on trade and investment in Japan.

F. **Special Zones for Regulatory Reform:** The Government of Japan has implemented 214 proposals under the Special Zones for Structural Reform program and will continue to promote the system. It will also continue to take the necessary steps to apply successful regulatory exemptions in the Special Zones on a national basis as quickly as possible (as of March 2008, 123 Special Zone measures have been applied nationwide) and will continue to consult with local governments and other concerns including domestic and

foreign companies to expand implementation of the Special Zone system. In these situations, a committee evaluates regulatory exceptions for the special zone. Furthermore, if it is judged that local revitalization is significant, the special zone should be continued. Information about the Special Zone system will continue to be provided in English to the extent possible. With regard to regulatory exceptions in the area of medical care under the Special Zone system, the Government of Japan will continue to monitor the current situation and, if received, will consider requests for expansion.

G. **Government Practices Relating to Agriculture**

1. Organic Crops:

- a. *Assessment of Substances Used for Organic Crop Production:* After having examined scientific data provided by the Government of the United States on Lignin sulfonate and Potassium bicarbonate, the Government of Japan held an explanatory meeting on May 16, 2008, with consumers to receive views on the possible removal of these substances from the list of three substances identified by the Government of the United States. The Government of Japan will seek public comments starting before July 1, 2008, in order to make a final determination on whether to permit these substances. The Government of Japan is also reviewing the data on Humic Acid as provided by the Government of the United States in order to proceed with the same process as described above.
- b. *Setting Tolerance Level of Prohibited Pesticide Residue for Organic Crop Production:* The Government of Japan explained to the Government of the United States that setting a tolerance level of prohibited pesticide residue for organic production is the issue that should be discussed at some multilateral fora. The Government of Japan recognizes the view of the Government of the United States that the relevant international standard setting body, Codex Alimentarius, has already provided a guideline on the issue of tolerance levels for pesticide residue for organic production and that this guideline does not support a zero tolerance level. Both the Governments of Japan and the United States will continue to discuss this issue bilaterally on the basis of the Codex guideline as well as through further consultation with Codex in order to resolve the concerns of the United States.

2. Import Regime for Maximum Residue Limits (MRLs):

- a. With regards to its enforcement of imported products for pesticide residues, the Government of Japan, taking into consideration the effectiveness of the U.S. system for regulation of pesticide residues, agreed to impose a measure exclusively against the specific violator (exporter) concerned, in cases that the maximum residue limit (MRL) in the United States of the agricultural chemical and commodity in question is equal to or lower than

the MRL in Japan, because the Government of Japan has concluded that U.S. system provides at least the same level of protection as is required in Japan.

- b. Regarding violations in cases where the U.S. MRL is higher than Japan's, the Japanese side explained that its decisions will be made on a case-by-case basis. The Government of the United States continued to request that the Government of Japan agree to limit its enhanced testing requirement to the violating shipper as a general policy.
- c. The Government of Japan and the Government of the United States will continue consultations to seek a solution to address cases where the U.S. MRL is higher than that of Japan.

3. Food Additives:

- a. The Government of Japan is proceeding with the authorization review for the 46 food additives and flavorings that are widely used and have been internationally confirmed as safe (for example, by the FAO/WHO Joint Expert Committee on Food Additives (JECFA)). Since 2003, following an evaluation results of the Food Safety Commission (FSC), the MHLW has approved the use of 13 food additives and 15 flavorings.
- b. The designation of six additives, including polysorbates, was announced on April 30, 2008, and these additives were approved for use in Japan. The United States and others requested an accelerated review process for these additives. Regarding the review of the remaining substances, MHLW will continue to conduct its review process expeditiously, and continue to work cooperatively with the FSC to make the process as efficient as possible.
- c. The Government of Japan also reported the risk assessment of Valeraldehyde and Isovaleraldehyde was completed by the FSC, and MHLW will start its discussion on these flavorings under the Pharmaceutical Affairs and Food Sanitation Council in the near future.
- d. The Government of Japan seeks the cooperation of its trading partners by requesting specific data, as needed, so as to advance promptly and smoothly evaluations by relevant Government of Japan reviewing organizations.

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

5. Cosmopolitan Pests Review:

- a. On May 20, 2008, the Government of Japan notified the WTO regarding the potato aphid (“*Macrosiphum euphorbiae*”). As a result, the potato aphid will be treated as a non-quarantine pest concerning lettuce for consumption.
- b. The Government of Japan will continue its pest risk analyses (PRAs) to determine the quarantine status on the cotton and bean aphids, the remaining two pests of priority interest to the Government of the United States, based on international standards. The Government of Japan will continue efforts to harmonize the classification of cosmopolitan pests with international standards.

IX. PRIVATIZATION

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”) are disclosed under the same regulations as other private sector companies, including those under the Companies Act, Banking Law, Insurance Business Law, other related laws and ordinances, and, when engaging in public capital market transactions, the Financial Instruments and Exchange Law . The Financial Services Agency (FSA) has sole authority over the supervision and inspection of Japan Post Bank and Japan Post Insurance under the Banking Law and Insurance Business Law, and applies the same standards as those applied to other banks and insurance companies, including when engaging in sales and distribution of financial services or insurance products. Accordingly, measures are implemented to ensure that the privatized postal financial institutions meet the same licensing, disclosure, and supervisory requirements as private sector financial institutions, including requisite risk management and full FSA supervision. Therefore, the FSA established a new office with a director and 11 more staff in its Supervisory Bureau. Furthermore to strengthen the supervision of Japan Post Bank and Japan Post Insurance, the FSA will engage one additional Director for the supervision of Japan Post Insurance and four staff members for the supervision of Japan Post Bank and Japan Post Insurance. The Government of Japan will continue to ensure that the FSA properly regulates the postal financial entities under all regulations applied to other banks and insurance companies. The relationships and transactions among Japan Post Bank, Japan Post Insurance, Japan Post Holdings, and Japan Post Network, are required to meet the obligations under the Banking Law and Insurance Business Law, including with respect to the arms-length rule. For purposes of accounting

regulation under the Banking Law and Insurance Business Law, these four companies meet the “special relationship” criteria under the requirements of these laws.

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

reinsurance contracts. As of October 2007, these deposit and reinsurance contracts are subject to the Banking Law and Insurance Business Law as well as to FSA inspection and supervision and are on a commercial basis. The FSA and the Ministry of Internal Affairs and Communications (MIC), under their respective authority, ensure that revenues associated with the reinsurance contract and profits 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.

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

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

C. Level Playing Field for Express Carrier Services

1. The same "duty declaration" system will be applied to customs clearance procedures for international physical distribution services provided by 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 by the end of March 2009 the "duty declaration" system to international postal items that are valued at over 200,000 yen. In order to apply the "duty declaration" system by this deadline, preparations are being made to implement this new approach; for example, Japan Post Service is reviewing its processing operations and is providing training to its staff.

2. 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.
3. 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.
4. Recognizing the importance of transparency in considering an international physical distribution business expansion request by Japan Post Service, the Postal Services Privatization Commission (PSPC) sought opinions from various parties by accepting public comments and holding a hearing on May 14, 2008, in which interested parties, including the American Chamber of Commerce in Japan, expressed their views. In its meeting on June 11, 2008, the PSPC included in its list of points for discussion some of the issues raised by the foreign business community, including the treatment of EMS.
5. Supervision by the Ministry of Land, Infrastructure, Transport, and Tourism (MLIT) of the new Japan Post entities and their related operations, including EMS services by Japan Post Service, is being applied according to the same standards as those applied to private companies.

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 available 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. It is prescribed by the Law of the Privatization of the Postal Services that the PSPC will implement the review about the progress of the Japan Post privatization every three years, and the deadline of the first review is the end of March 2009. The Government of Japan is aware of the view of the Government of the United States that this review should be comprehensive and will include opportunities for all interested stakeholders to express views, including with respect to the impact of the reforms in the banking, insurance, and express delivery markets and on the equivalence of conditions of competition between the new Japan Post companies and the private companies in these sectors. 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, including on such issues as the conditions of competition between the new Japan Post entities and the private sector. 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 as public comments are solicited.
3. Under the Standing Order of the PSPC, the PSPC has made publicly available summaries of meeting minutes as well as detailed meeting minutes in a timely manner. For each of its meetings to date, the PSPC has made the agenda items publicly available prior to the meeting, and has held the post-meeting press briefing. The Secretariat of the PSPC will continue to support the PSPC's efforts to maintain transparency in the Committee's discussions on postal services privatization. For example, the Secretariat of the PSPC will continue to make advance notice of the PSPC's agenda items publicly available (including on the relevant website) prior to each PSPC meeting.
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:** The Government of Japan and the Government of the United States exchanged views regarding user fees at airports in Japan.

B. Improving Efficiency in Customs Processing

1. Two-staged Declaration of Import: The Government of Japan revised the Customs Law in 2008 to allow inclusion of authorized customs brokers in Japan's Authorized Economic Operators (AEO) program. The program enables the declaration of cargo release and the declaration of duties and taxes to be filed separately.
2. Postmortem Declaration of Imports: The Government of Japan takes note of the view of the Government of the United States regarding postmortem declaration of exports.

3. Freedom of Selecting Customs Office for Declaration: 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.
 4. Reduction of Overcharge Costs and NACCS Charges: The Government of Japan has eliminated the overtime service charge and simplified the application procedure for overtime service.
- C. **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.
- D. **Parking for Distribution Vehicles**
1. The new Road Traffic Law and related enforcement guidelines, which took effect in June 2006, have been as successful as expected in reducing traffic jams, accidents and illegal parking.
 2. 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 vehicle before affixing a ticket. Stopping within five minutes for the purpose of loading and unloading of cargo is legally permitted.
 3. The National Police Agency (NPA) recognizes the requests for deregulation measures from the industry, including U.S. industry. NPA gives instructions to each Prefectural Police department to review enforcement of parking regulations and parking permit procedures concerning cargo vehicles.
 4. Each Prefectural Police department, if appropriate, excludes cargo vehicles from being regulated when they inevitably need to handle packages on the side of the road and has also adopted measures such as placing parking meters for cargo vehicles in order to respond to the parking demands.
 5. The Government of Japan will continue to improve urban facility and traffic management by:
 - a. Cooperating with relevant authorities to promote parking space development such as stopping lane to load and unload; and
 - b. Recommending that local governments establish ordinances to provide parking facilities, including parking for commercial vehicles, in newly constructed or newly renovated buildings of a certain usage and size.

E. Laws Affecting Large Scale Retail Stores

1. The Central City Invigoration Law aims to improve urban functions and the economic vitality of central cities through plans developed and carried out by municipalities based on community needs. The intention of the Law is not to restrict plans by large scale retailers to open new stores.
2. The Government of Japan will review the impacts of the Central City Invigoration Law within ten years as stated in the law, and in that process make public views about the operation and impacts of the Law.
3. The Government of Japan explained to the Government of the United States that the impact of the amended City Planning Law, which fully came into effect on November 30, 2007, will be reviewed and published in a timely manner taking into account the views of private sector as well as other relevant entities. While the Government of Japan has not yet determined the scope and timing for this review, the Government of Japan is aware of the view of the Government of the United States regarding the importance of ensuring that the opinions of all interested parties are solicited in this review process in order for Japan to be able to assess the overall effects of these reforms.

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 Japan and the United States have a disagreement as to the existence or consistency with a covered agreement of measures taken to comply.
- 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. 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. DISTRIBUTION AND CUSTOMS PROCEDURES

- A. **Maritime Transport Security:** The U.S. Department of Homeland Security (DHS) and counterparts in the Government of Japan have worked through the U.S.-Japan Sub-Cabinet Economic Dialogue Study Group on Secure and Efficient Trade to address issues regarding supply chain security initiatives. These exchanges have included video conferences and a visit by DHS to Tokyo in November 2007 to explain to Japanese officials and industry groups how the multiple DHS security initiatives build on one another to advance a layered security strategy and risk-management approach to the global supply chain. Recognizing that information gathering and international cooperation are key to successfully securing the supply chain, DHS expects to continue productive discussions on these issues through the Study Group on Secure and Efficient Trade.

1. 100 Percent Scanning Requirement for U.S. Bound Cargo Containers:

- a. As required by the Security and Accountability for Every (SAFE) Port Act,

DHS has submitted a report to Congress detailing the efforts undertaken and lessons learned under the Secure Freight Initiative Phase I. The report includes input and concerns from the private sector and international partners. A report was made available to the Government of Japan.

- b. DHS will be responsive to legislation passed by Congress. In fulfilling Congressional requirements, DHS is committed to developing a practical approach towards 100 percent scanning that acknowledges and overcomes challenges encountered in the first phase of radiological/nuclear scanning deployments.
- c. The Government of the United States is aware that the Government of Japan has serious concerns with 100 percent scanning and its potential impact on international trade and economic activities as a whole. DHS is committed to working with domestic and foreign partners, trade, and industry to address 100 percent scanning in a responsible and logical manner that integrates smoothly into the global trade supply chain. DHS looks forward to continuing constructive discussions with the Government of Japan under the Study Group on Secure and Efficient Trade.

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

- a. The C-TPAT program continues to evolve with respect to providing facilitation benefits to importer partners in return for proof of strong supply chains. Today, C-TPAT has established a three tiered system to provide benefits to its Importer partners. Tangible benefits for importer C-TPAT partners include:
 - (1) The potential for a lower targeting score (fewer inspections).
 - (2) The potential for an expedited inspection (front of the line). C-TPAT importers are afforded “front of the line” inspection privileges in all modes of transportation to the extent possible and practical.
 - (3) The assignment of a Supply Chain Security Specialist (a direct point of contact in CBP).
 - (4) The potential for expedited processing in instances of supply chain disruption (business resumption).
 - (5) Dedicated lanes on the southern and northern borders. C-TPAT approved carriers, carrying qualifying goods from a C-TPAT approved importer, are able to use these dedicated lanes under the Free and Secure Trade program - FAST.

- (6) Being eligible for account based processing (e.g. bimonthly/monthly payments) and future CBP programs.
 - (7) Reduced insurance costs; better inventory management; reduced cargo theft and employee pilferage; increased profits; maintaining and projecting corporate image in alliance with CBP.
 - b. CBP and the C-TPAT program must comply with SAFE Port Act legislation in its application of all benefits and while the program will continue to look for additional benefits, current and new benefits must be administered in the spirit of the act and must be thoughtfully created.
- 3. 24-hour Rule on Advance Manifest Presentation:
 - a. In meetings with the Government of Japan, DHS has explained its obligations to implement the 24-hour rule, including that the 24-hour rule relates only to the submission of advance cargo declarations and does not require the physical presence of the containers themselves (and that, as a measure of flexibility, last-minute changes to cargo manifest data are contemplated and permitted). The Government of the United States notes that the Government of Japan has expressed concerns that the 24-hour rule may lead to longer lead times and the reduction in distribution efficiency.
 - b. The Government of the United States welcomes the Government of Japan's enhancement to Japan's AEO program which will allow customs brokers, in addition to authorized exporters, to file export declaration to Japanese Customs prior to cargo being physically present in *HOZEI* (bonded) areas. It is expected that this enhancement will contribute to shortening already extended lead time at Japanese seaports. The Government of the United States appreciates the Government of Japan's efforts to work with Japanese industry to implement these changes. The Government of the United States understands that Japanese industry has technical and logistical issues it needs to address in order to meet 24-hour rule requirements with minimal impact on trade flows. DHS will continue discussion with the Government of Japan on these issues through the Study Group on Secure and Efficient Trade.
 - c. Customs and Border Protection (CBP) published a Notice of Proposed Rule Making (NPRM) on the topic of Advance Security Filing, also known as "10+2", in the Federal Register on January 2, 2008. DHS appreciates the feedback provided by the Government of Japan. As part of the NPRM process, DHS will carefully consider all comments, including those of the Government of Japan and Japanese industry, submitted during the public comment period in developing a practical rule that balances security and the free flow of legitimate commerce.

B. **Merchandise Processing Fee:** The United States' Merchandise Processing Fee (MPF) is limited in amount to the approximate costs of services rendered. The Government of the United States takes note of the Government of Japan's recommendation regarding the MPF.

C. **Measures against Bioterrorism**

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 Government of 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. In response to the Government of Japan's recommendation, the U.S. Embassy to Japan has added to its website information on bioterrorism related rules and procedures, and has identified points of contact at the Embassy who can answer any additional questions in this field.

D. **Increase in U.S.-Mexico Customs Clearance Lanes**

1. President Bush in March 2007 set up the U.S. Border Facilitation Working Group to address the wide and interconnected issues related to delays at the border. This interagency group has met with Mexican counterparts and identified a set of concrete actions to improve infrastructure and staffing at targeted ports of entry. These include hiring 800 new staff, harmonizing hours of operation, adding trusted traveler lanes and launching a pilot project of mobile inspection booths.
2. In some places, Customs and Border Protection (CBP) has been able to add lanes, including Otay Mesa, which added two additional FAST (Free and Secure Trade Program) lanes in the last few months to bring the total number of commercial primary lanes to ten. However, it is not always possible to do so or to do so quickly, as most of the U.S. ports of entry are not owned by the Federal Government, but rather are owned by state and local officials and private businesses. Expansion at many U.S. ports of entry is also constrained by available space. The hours of operation at the Otay Mesa facility are set in conjunction with the Government of Mexico, as the U.S. side cannot be open while the Mexican side is closed.
3. U.S. inspectors at ports of entry face on a daily basis threats whose detection requires vigilance and attention to detail. Like many other Agencies, CBP has to balance its mission and services with its available resources. While CBP's first priority is counter-terrorism, it is also responsible for carrying out the traditional missions of the predecessor agencies that make up U.S. Customs and Border Protection.
4. Border wait times vary considerably by time of year (holiday/seasonal) and day of week, as well as by time of day. The most accurate estimate of current wait times is provided at CBP's website: http://www.cbp.gov/xp/cgov/travel/wait_times/.
5. The Government of the United States takes note of the request by the Government of Japan to make customs procedures as expeditious and smooth as possible.

E. 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 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. If entry standards for imported beverage products are met then the imported product should not have a problem clearing United States Customs and Border Protection. This applies to products being cleared via a COLA or an approved COLA Waiver Request per long-standing practices.

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. Although retail sales of alcohol beverages mainly fall under the jurisdiction of State law, the Government of the United States has forwarded to the States of California and New York the recommendations raised by the Government of Japan.
 - c. In the State of New York, S.6911/A.10116 has been introduced in the State Legislature. This legislation would amend the Alcoholic Beverage Control Law to permit persons licensed to sell wine at retail for consumption on the premises to sell certain low-alcohol beverages. For the purposes of this legislative proposal, "certain low alcohol liquors, spirits, distillates and other alcoholic beverages" shall mean any liquors, spirits, distillates and other alcoholic beverages that contain not more than twenty-four per centum alcohol, by volume, that are derived from agricultural products.

III. CONSULAR AFFAIRS

A. Visa Processing

1. “Visa Waiver Program Modernization” Provision: Section 711 of the “Implementing Recommendations of the 9/11 Commission Act” (9/11 Act) provides four mandatory security enhancements to the Visa Waiver Program (VWP) which affect both current VWP countries and those that aspire to participate in the VWP: use of an Electronic System for Travel Authorization (ESTA); agreement with the United States to exchange passenger information; agreement with the United States to report blank, as well as issued, lost and stolen passports; and repatriation of citizens no later than three weeks after a final order of removal is issued. In implementing the statutory requirement, the Government of the United States will take into consideration the dual goals of “secure borders and open doors,” while at the same time facilitating legitimate travel.
 - a. In response to the Government of Japan’s request for details on the ESTA system, the Government of the United States in June 2008 provided the Government of Japan with an explanation about how the ESTA system will be implemented. The Department of Homeland Security (DHS) is also working closely with the Departments of State and Commerce to develop a comprehensive outreach plan to communicate the ESTA requirements to all affected travelers and related stakeholders.
 - b. The Government of the United States requested that the Government of Japan implement the other mandatory measures outlined above no later than October 2009 in order to remain eligible for the VWP. Current agreements, arrangements, and/or practices that satisfy these requirements will be taken into account.
 - c. There are also three discretionary enhanced security factors included in the 9/11 Act: airport security standards; air marshals programs; and standards for national travel documents. DHS will take these discretionary measures into consideration when conducting the statutorily mandated biennial country reviews of current VWP members for continuing designation. As an example, Japan already adheres in part to the airport security standards factors which are stipulated in the 9/11 Act through its participation in the DHS Customs and Border Protection’s Immigration Advisory Program at Narita Airport and its compliance with International Civil Aviation Organization standards.
 - d. DHS is requiring each VWP country to sign a memorandum of understanding (MOU) outlining its intent to comply with the new security provisions outlined above. DHS is also requiring each VWP country to enter into implementing arrangements for the enhanced information exchange, unless other arrangements or agreements already in place fulfill the new security requirements of the VWP legislation.

- e. Officials from DHS have met with representatives of the Government of Japan to discuss the VWP MOU text and new VWP security requirements and DHS expectations for compliance were discussed.

2. Efficiency in Visa Reissuance Procedures:

- a. The U.S. Department of State halted visa reissuance in the United States in July 2004, among other reasons, due to the requirements to issue biometric visas and interview almost all applicants in person. Under U.S. law, the U.S. Department of State's visa office cannot collect domestic biometrics or conduct domestic adjudication of visas.
- b. The Government of the United States acknowledges the concerns that have been raised by the Government of Japan about the impact of this decision on visa holders. The Government of the United States does not plan to resume domestic reissuance of visas. The Government of the United States is studying options other than domestic reissuance of visas to address these concerns.
- c. The Government of the United States explained that applicants can extend their stay in the United States without renewing their visas by applying for an extension with the Department of Homeland Security. However, when the applicant departs the United States, he or she will need to reapply for a visa at a U.S. Embassy or Consulate abroad. The Government of the United States is aware of the view of the Government of Japan that this requirement under U.S. law may affect business travel.
- d. The Government of the United States explained that applicants are encouraged to apply for new visas in their home countries but may apply in a third country, provided they make a visa interview appointment. The Government of the United States is aware of the Government of Japan's request to allow for reissuance of E visas in certain third countries.
- e. Visa procedures at the U.S. Embassy and consulates in Japan are efficient and smooth. The average wait time for a visa appointment in Tokyo is one to two days, and the Embassy in Tokyo typically requires one additional day to issue visas that are approved. At present, wait times are similar in other U.S. Consulates in Japan. Wait times at third country posts can be determined by using the State Department's consular affairs website.
- f. The U.S. Department of State is seeking final approval to institute new procedures that may help some applicants renewing visas. These procedures would expand the number of persons who are eligible to apply for visas without having to appear in person at the embassy or consulate that adjudicates their visa application, provided that they are physically present and submitting their application in their country of residence or

nationality abroad. Once important details about these changes are worked out, the U.S. Department of State will make public an announcement about the program. For these procedures to be applicable, the applicant must have already submitted all ten fingerprints, have been interviewed by a consular officer, and be applying for a new visa in the same category within 12 months of their previous visa's expiration. The Government of the United States is aware of the Government of Japan's request that applicants in the United States be allowed to apply for reissuance of visas in Japan through international mail.

3. Improvement of Visa Services in Japan:

- a. 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 in the United States Consulate in Sapporo and Fukuoka. Sapporo schedules 25 appointments per two appointment days per month to meet the demand and Fukuoka has a similar schedule.
- b. The Government of the United States provides a very favorable level of U.S. consular services in Japan, with five non-immigrant visa processing missions, compared to other countries. Moreover, the wait time for an appointment in Tokyo is one day for tourist/business visas and one day for student/exchange visitor visa.
- c. There are currently no plans to accept visa applications at the U.S. Consulate in Nagoya. Nagoya is only 163 miles in distance from Tokyo and 81 miles in distance from Osaka, and the three cities are linked by highly developed rail and highway networks. The Government of the United States always seeks to provide excellent consular service in all of its overseas posts, including the five nonimmigrant visa processing posts in Japan.

4. Visa Issuance and Terms of Validity:

- a. The validity of the intra-company (L) visa is limited by statute. The L-1 employed in a specialized knowledge capacity is limited to five years and the L-1 employed in a managerial or executive capacity to seven years. Visas cannot be revalidated past that point and no further extensions may be granted once these limits have been reached. Any changes in law pertaining to L-1 visas must be implemented by the U.S. Congress.
- b. The validity of H-1B visas and their annual quotas are also controlled by the U.S. Congress. The law limits an H-1B nonimmigrant to a maximum length of stay of six years.

- c. Holders of L-1 and H-1B visas may lawfully apply to adjust their status to become legal permanent residents (LPRs) in the United States. Every year a large number of nonimmigrant visa holders adjust their status in the United States to employment-based immigrant status.
- d. The Department of Homeland Security (DHS) may extend an H-1B visa holder's six-year duration of status limit in one year increments if the visa holder has an employment-based immigrant petition or an adjustment of status application pending and it has been more than 365 days since the labor certification application or the petition was filed.
- e. It is possible for companies that intend to keep employees in the United States for several years to file an immigrant visa petition for the employee soon after he or she arrives in the United States on an L or H visa. U.S. law does permit an alien to work in the U.S. on a nonimmigrant visa while pursuing an immigrant visa.
- f. U.S. law contemplates that family members of LPRs who wish to accompany and reside in the United States with LPRs should apply for legal permanent residence in the United States. Alternatively, an LPR could give up his/her residency status and obtain a work visa. These limits are set in statute (presumption of immigrant intent) and DHS regulations (LPRs cannot also hold non-immigrant visas).
- g. With respect to the Government of Japan's request concerning the requirement that L-1 applicants must occasionally submit the organization chart of their companies specifying the names of employees, their titles and salaries, the Government of the United States acknowledges the Government of Japan's concerns about privacy protection and notes that consular officers request only that additional information which is necessary to determine whether the applicant meets the requirements of the visa category for which he/she is applying.

B. Driver's Licenses

1. Real ID Act:

- a. The REAL ID Act, as enacted, specifically states that "A temporary driver's license or temporary identification card issued pursuant to this subparagraph shall be valid only during the period of time of the applicant's authorized stay in the United States or, if there is no definite end to the period of authorized stay, a period of one year." The Department of Homeland Security (DHS) does not have the authority to interpret the meaning of terms used in the REAL ID Act in a manner inconsistent with the language of the Act or the intent of Congress.

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

2. Improvement of Handling of International Driver's Licenses:

- a. Pursuant to the 1949 Convention on Road Traffic, to which both the United States and Japan are party, Japanese nationals traveling through the United States may drive using valid driver's licenses issued by Japanese authorities for a period up to one year. If, however, a Japanese national becomes a resident of a U.S. state, he/she must respect the residency laws/regulations of the state in which he/she resides. These residency laws may include obtaining a state driver's license within a certain period as a condition for continued authorization to drive. Requiring that persons seeking the benefits of residency comply with relevant regulatory requirements of the jurisdiction in which they choose to reside is consistent with U.S. obligations under the Convention.
- b. The Government of the United States is not aware of any states' regulations that, unrelated to residency requirements, provide that international driving permits or foreign driver's licenses lose their validity in a short period of time.

3. Improvement of State Rules:

- a. The U.S. Department of State communicated the Government of Japan's concerns regarding driver's license procedures to the State of Georgia. The Georgia State Legislature introduced SB 488, a bill to amend Georgia state law so as to allow foreign nationals to keep their licenses from their home countries. SB 488 was passed by both houses of the Georgia State

Legislature on April 11, 2008, and signed into law by Governor Sonny Perdue on May 18, 2008. The new law will take effect on January 1, 2009.

- b. The U.S. Department of State communicated the Government of Japan's concerns regarding driver's license procedures to the Office of the Ombudsman at the Massachusetts Registry of Motor Vehicles. The Office of the Ombudsman stated that the sponsor requirement is applied to all drivers, regardless of nationality, who take the local driving exam. The Office of the Ombudsman wished to stress that the Massachusetts Registry of Motor Vehicles is very sensitive to the needs of foreign drivers, and invests a great deal of resources in efforts to verify international documentation and provide assistance to foreign drivers in the state.
- c. The U.S. Department of State communicated the Government of Japan's concerns regarding driver's license procedures to the State of Kentucky.
- d. The U.S. Department of State communicated the Government of Japan's concerns regarding driver's license issues to the State of New York. New York's Department of Motor Vehicles informed the U.S. Department of State that New York driver's licenses are valid until the expiration date listed on the license, regardless of the period of authorized stay listed on the license. However, the State of New York asks that foreign drivers who obtain extensions of stay or who change their legal status submit documentation of such changes to their local Department of Motor Vehicles offices, in order to have their licenses updated to reflect these changes.

C. **Immigration Control**

1. Immigration Procedures:

- a. U.S. Customs and Border Protection (CBP) of the Department of Homeland Security (DHS) introduced the SENTRI program to provide expedited CBP processing for pre-approved, low-risk travelers. SENTRI users have access to specific, dedicated primary lanes into the United States from Mexico. More than 155,000 travelers from both sides of the border currently are enrolled in the program.
- b. CBP is responsive to the needs of travelers under the SENTRI program. In the last two years, CBP has expanded locations to now include 16 lanes at the nine largest ports of entry along the U.S.-Mexico border including San Ysidro, CA; Otay Mesa, CA; Calexico, CA; Nogales, AZ; two crossings in El Paso, TX; Laredo, TX; Hidalgo, TX; and Brownsville, TX. CBP recently expanded SENTRI lane hours at the El Paso port of entry, to 24/7 at the Ysleta border crossing and added two additional hours per day during the weekdays and six additional hours per day during the weekend.

CBP also added a new SENTRI lane at the Laredo port of entry in April 2008.

- c. CBP recently launched an on-line application and fee payment process which has reduced application processing times at San Diego from 18 months to four to six weeks. CBP extended the SENTRI enrollment period from two years to five years with no increase in fee. CBP has improved identification recognition by introducing radio frequency (RF) technology in its Trusted Traveler lanes, and plans to install this technology in all lanes at the busiest land border ports of entry as part of the Western Hemisphere Travel Initiative.

2. Consistency of Immigration Inspection Procedures: Customs and Border Protection Officers are fully informed and trained on all relevant laws and policies related to immigration related procedures in the United States.

D. **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. Premium processing service may be requested which guarantees fifteen calendar day processing for an additional fee of \$1,000. This option is only available for extension requests which are filed in conjunction with the filing of a Form I-129, Petition for Nonimmigrant Worker. Premium Processing Service is not available for stand-alone Form I-539 Applications to Extend/Change Nonimmigrant Status which are not filed concurrently with a related Form I-129.
2. Extension and Automatic Renewal of Validity of Permission to Stay:
 - a. The Government of the United States recognizes the request of the Government of Japan to extend the term of validity of the Permission to Stay (I-94). U.S. Citizenship and Immigration Services (USCIS) has prioritized backlog elimination since FY2006, and has made significant strides towards accomplishing its backlog elimination goals.
 - b. 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.

- c. 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.

E. Social Security Number

1. Expeditious Issuance of Social Security Number: The Social Security Administration (SSA) understands the need for expeditious issuance of social security numbers (SSNs) in all communities. SSA has seen an increase in the number of SSN card applications where the Department of Homeland Security's (DHS) Systematic Alien Verification for Entitlements (SAVE) initial verification response confirming a non-citizen's immigration status is immediately obtained. It has also been its experience that the DHS responds to SSA's SAVE electronic additional verification requests within three to four days. However, there still remain a small percentage of cases where verification may take additional time because DHS must search for additional information manually.
2. Issuance of Social Security Numbers to Dependents of Employment Visa Holders:
 - a. SSA recognizes a non-citizen as eligible for a SSN if they have DHS work authorization or if they have a valid non-work reason for an SSN. To ensure standardized operation and application of the enumeration process, SSA Field Office personnel receive refresher training and/or policy reminders on how to process SSN card applications for non-immigrants, by alien class of admission codes.
 - b. In some situations proof of marital relationship to certain individuals authorized to work is acceptable in lieu of proof of the individual's authorization to work (Employment Authorization Document – EAD). When a dependent (spouse of E-1, E-2 or L-1) applies for an SSN without having obtained an EAD, he/she must submit, in addition to evidence of immigration status (Form I-94 in combination with the foreign passport), evidence of a marital relationship with the principal. In these situations evidence of a marital relationship is generally a marriage document indicating the marriage occurred prior to admission to the United States. Since in Japan the Family Registry is the official form used to establish evidence of marriage, SSA accepts the Japanese Family Registry as evidence of marital relationship. SSA generally accepts translations of the Japanese Family Registry issued by the Japanese Embassy/Consulate. 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.

- F. **Residency Certification:** The income tax treaty between the Governments of the United States and Japan provides certain benefits, such as reduced rates of withholding tax, for qualified residents of either country. Although the Government of the United States allows foreign persons to “self-certify” that they are a foreign person eligible for a reduced rate of withholding under the treaty, the Government of Japan requires that the IRS certify that the person claiming treaty benefits is a resident of the United States. The IRS provides this residency certification on Form 6166 (which is a letter printed on U.S. Department of Treasury stationery certifying that the individuals or entities listed are residents of the U.S. for federal income tax purposes). Form 8802 (Application for United States Residency Certification) is used to apply for Form 6166). The IRS has introduced an online application system for Form 6166. The IRS has been striving to simplify the Form and to make it more user-friendly.

IV. INVESTMENT-RELATED REGULATIONS

- A. The Government of the United States has taken a number of significant steps to reform and improve the process through which the Committee on Foreign Investment in the United States (CFIUS) reviews certain foreign investments in U.S. businesses to determine their effects on the national security of the United States. These reforms, which include the Foreign Investment and National Security Act of 2007 (FINSAs), Executive Order 11858 (as amended on January 23, 2008), and proposed CFIUS regulations issued by the U.S. Treasury Department on April 21, 2008, helpfully provide foreign investors greater transparency and certainty regarding the CFIUS process. As required by FINSAs, the U.S. Treasury Department will also be publishing later this year guidance on what types of transactions have been filed with CFIUS and raised national security considerations.
- B. The amended Executive Order increases transparency and predictability of the process by defining the relationship between CFIUS and the President and the roles of the chair of CFIUS, lead agencies, and other CFIUS members. It also requires that CFIUS apply additional analytical and procedural rigor before imposing any risk mitigation conditions on a transaction. The proposed regulations, which update CFIUS regulations issued in 1991, implement section 721 of the Defense Production Act of 1950 (section 721), as amended by FINSAs, and the amended Executive Order. The proposed regulations further increase transparency and predictability by clarifying numerous procedural rules and what transactions are covered under FINSAs. The U.S. Treasury Department will accept public comments on the proposed regulations through June 9, 2008, and will issue final regulations after considering all comments received. Section 721, as amended by FINSAs, and the proposed regulations continue to require CFIUS to maintain the strict confidentiality of all information filed with CFIUS, in order to protect sensitive business information and classified U.S. government information.
- C. The Government of the United States shares the view with the Government of Japan that transparency, predictability, and accountability are critical elements for investment-related regulations.

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 a point of discussion in the United States. Legislation is currently pending in both the U.S. House of Representatives and the U.S. Senate (H.R. 1908 and S. 1145), which contemplates a change in U.S. law from first-to-invent to first-to-file. The House of Representatives passed H.R. 1908 on September 7, 2007, and the companion bill in the Senate was endorsed by the Senate Judiciary Committee. The United States will continue to provide updates on the status of legislation as appropriate. In addition to these legislative efforts, the United States continues to pursue harmonization in discussions with Japan and other World Intellectual Property Organization (WIPO) Group B member countries concerning a possible substantive patent law agreement, the relevant draft provisions of which are written from a first-to-file perspective.
- B. **Early Publication System:** The pending legislation in both the House and Senate address this issue. S. 1145 requires publication for all pending applications at 18 months, which is consistent with the views of the Government of Japan. H.R. 1908 retains a modified version of the exception by requiring publication at the later of 18 months or three months after second office action. The United States will continue to provide updates on the status of legislation as appropriate.
- C. **Reexamination System:** The Government of the United States recognizes that ex parte and inter partes reexamination limit interaction and only apply to specific grounds of patentability. New provisions in the proposed legislation (H.R. 1908 and S. 1145) contemplate post-grant opposition proceedings that would expand the scope of post-grant review.
- D. **Restriction Requirement Due to Non-Fulfillment of Unity of Invention:** The Government of the United States recognizes that its restriction practice, as applied to non-Patent Cooperation Treaty (PCT) applications, differs from unity of invention practice under the PCT. The Government of the United States continues to study these differences in practice, but notes that applicants filing with the U.S. Patent and Trademark Office (USPTO) have a choice to file either a national application or through the PCT in order to receive treatment according to either U.S. restriction practice or PCT unity of invention practice.
- E. **Hilmer Doctrine and Article 102(e) of the Patent Act:** The Government of the United States recognizes that the Government of Japan has concerns regarding the Hilmer Doctrine and Article 102(e) of the Patent Act. It should be noted that the legislation introduced in the House and Senate addresses this issue favorably from the perspective of

the Government of Japan. Furthermore, the United States continues to discuss this issue in patent law harmonization talks with Japan and other World Intellectual Property Organization (WIPO) Group B member countries.

- F. **Information Disclosure Requirement of Prior Art:** The Government of the United States acknowledges and continues to consider the Government of Japan's concerns over USPTO Information Disclosure Statement (IDS) requirements. The Government of the United States notes the views of the Government of Japan and will continue to consider these views in relationship to the balance between imposing obligations on patent applicants on the one hand, and promoting a higher quality, more effective and efficient examination process on the other.
- G. **Plant Patent:** The Government of the United States acknowledges the concerns expressed by the Government of Japan regarding the manner in which the grace period provisions provided under the International Convention for the Protection of New Varieties of Plants (UPOV) interact with the grace period provided under U.S. law with respect to plant patents. There have been several bills introduced in the House and Senate in the past several years that would address these concerns, but none have been enacted. We will continue to consider the issue in view of the concerns expressed by the Government of Japan.

VI. GOVERNMENT PROCUREMENT

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.

- A. **Safe, Accountable, Flexible, Efficient Transportation Equity Act:**
 - 1. 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 these so-called "Buy America" restrictions attached to the Federal funds for those projects and thus the restrictions continue to apply.
 - 2. In September 2007, however, two changes were made to the mass transit regulation in a Department of Transportation/Federal Transit Administration final rule that may facilitate the participation of Japanese firms and address concerns raised by the Government of Japan. First, the consistent classification of components and subcomponents will permit U.S. transit agencies to acquire certain replacement parts from non-domestic sources. Second, the publication of

procedures for public interest waivers will expedite the processing of waivers for non-domestic rolling stock and end products.

- B. Defense Federal Acquisition Regulation Supplement:** The Department of Defense (DoD) continues to oppose the imposition of new domestic procurement restrictions by the U.S. Congress. In the National Defense Authorization Act of FY2008, Congress made changes to the specialty metals restriction in 10 U.S.C. 2533b that provide new flexibilities for DoD. For example, the new law contains a broader exception for electronic components and provides a new exception for commercial off-the-shelf (COTS) items with limitations on fasteners, castings and forgings and high performance magnets. Because the specialty metals restriction is very complex, the DoD will meet upon request with relevant Japanese officials to discuss the application of this law, as well as to clarify further the restrictions in the Buy American Act, that affect Japanese industry.
- C. Regulations Concerning Construction of U.S. Military Bases:** The Government of the United States acknowledged that the Government of Japan had concern on the “relocation of U.S. Marine Corps in Okinawa to Guam” and explained its view on this issue as follows:
1. Currently the Defense Federal Acquisition Regulation Supplement (DFARS) stipulated that military construction contracts to be performed in the U.S. territories in the Pacific and on Kwajalein Atoll, or in countries bordering the Persian Gulf shall be awarded only to U.S. companies unless the lowest tender offer of a foreign company is below the lowest tender offer of a U.S. company by more than 20 percent (DFARS 236.273). This stipulation applies to military construction works which are financed through the U.S. Military Construction Appropriations Act. Construction works which are financed by direct cash contribution from the Government of Japan and by loans to SPE (Special Purpose Entities), which are not financed through the U.S. Military Construction Appropriations Act, are out of the scope of this stipulation.
 2. It is currently anticipated that construction contracts financed by Government of Japan direct cash contributions will be above the threshold (7.4 million dollars) triggering application of the Trade Agreements Act (TAA). Stipulations of the Buy-American Act which oblige contractors to use U.S. products are not applied to contracts which are above the threshold of the TAA and such constructions projects are covered by the WTO Agreement on Government Procurement. Thus, companies of all countries who are signatory to the WTO Agreement on Government Procurement, including Japan, would be able to compete for contracts of such projects on an equal footing with U.S. companies.
 3. Regarding the laws and regulations which require the use of U.S.-Flag vessels for transportation of U.S. products (DFARS247.572), The Cargo Preference Act of 1904 is applied to the transportation of materials in all U.S. Department of Defense contracts. Therefore, materials associated with construction contracts financed by direct cash contribution from the Government of Japan will be subject

to the Cargo Preference Act.

4. Federal Acquisition Regulation requires contractors performing construction work ordered by the Federal Government to furnish bond for 100 percent of the contract price as performance guarantee and payment guarantee (FAR 28.1). This requirement is non-discriminatory as all contractors, including foreign contractors, are subject to the requirement. Therefore, construction works financed by direct cash contribution from the Government of Japan are subject to these requirements. In this regard, bonds issued by corporations incorporated under the laws of a State, the District of Columbia, or territory or possession of the United States, such as U.S. corporate subsidiaries of Japanese insurance companies, are valid if approved by the authorities concerned under U.S Treasury standards for bonding issuance (31 CFR 223.5). Cash or U.S Treasury securities are qualified as a substitute of performance guarantee.

VII. EXPORT-RELATED REGULATION

A. Export Licenses Procedures

1. On January 22, 2008, President Bush issued an Export Control Directive that will ensure that U.S. defense trade policies and practices better support the National Security Strategy of the United States. The package of reforms required under this directive will improve the manner in which the U.S. Department of State licenses the export of defense equipment, services and technical data, enabling the U.S. Government to respond more expeditiously to the military equipment needs of its friends, allies, and particularly our coalition partners.
2. The Export Control Directive mandates the commitment of additional financial and other resources, as well as procedural reforms, that will expedite the processing of export license applications for items controlled by the U.S. Munitions List. Although license processing times will be reduced as a result of this directive, the Government of the United States is committed to ensuring that existing measures to prevent the diversion of such items to unauthorized recipients remain strong and effective.
3. Specific actions directed by the President include the following:
 - a. Additional financial resources and intelligence support will be made available for the timely adjudication of defense trade licenses.
 - b. Guidelines will be issued that require a decision by the U.S. Government on defense trade export license applications within 60 days, absent a strong reason for additional time, such as a requirement for Congressional notification. Initial efforts in this regard have resulted in a nearly 50 percent reduction since April 2007 in the number of export license applications pending with the Department of State.

- c. The electronic licensing system will be upgraded to permit the submission of all types of defense trade licenses and to enable all agencies to access the same electronic information.
- d. The Secretary of State will update U.S. controls on exports involving dual and third country nationals from NATO and other allied countries.
- e. A formal interagency dispute mechanism will be created to allow for timely resolution of licensing jurisdiction issues involving the Departments of State and Commerce under the Commodity Jurisdiction (CJ) process. The National Security Council will also undertake a review to make sure the CJ process is efficient and timely.
- f. A multi-agency working group will be established to improve procedures for conducting export enforcement investigations.

B. Re-export Controls

1. The U.S. laws governing the development and implementation of U.S. re-export controls do not allow for the exemption of any specific country. However, in response to the Government of Japan's recommendations regarding U.S. re-export controls, the Bureau of Industry and Security (BIS) has:
 - a. Re-posted re-export guidance, translated into Japanese, on its website earlier this year; and
 - b. Hosted a two-day educational outreach seminar in Tokyo, and a similar one-day seminar in Osaka, in March 2008, both of which had a specific focus on re-export controls.
2. There is no legal requirement under U.S. law for U.S. companies to provide classification information, or Export Control Classification Numbers (ECCNs), to their customers. BIS has developed another way for U.S. exporters to share classification information and has:
 - a. Committed to the approach of adding a field to its electronic Classification Request application that would give applicants the option of having the results of their classifications published on the Bureau's website; and
 - b. Started to explore a way for applicants to have the results of previously issued classifications posted to the Bureau's website.
3. The U.S. Government will continue to study and discuss the ECCN issue in light of the issues raised by the Government of Japan.

VIII. STANDARDS AND CRITERIA

A. Metric System

1. The U.S. National Institute of Standards and Technology (NIST) will continue to promote the use and benefits of the metric system in trade and commerce within the United States. Working with the U.S. Metric Association (a private sector organization) and other partners, NIST provides public information through websites and other tools, outreach efforts, and responds to thousands of inquiries annually to educate the public and industry.
2. Today, 96 percent of U.S. states permit metric units on packages subject to their jurisdiction. Products include all those not subject to federal regulation, such as automotive accessories, clothing and wearing apparel, and household furnishings. The State of New Jersey announced in 2007 that it would permit metric-only units on packaged goods, leaving only two U.S. states with legal prohibitions against metric-only labeling on consumer product packages. NIST, along with other organizations, continues its outreach activities with these remaining states.
3. New technologies present opportunities for expanding the use of the metric system. For example, the U.S. National Work Group for the Development of Commercial Hydrogen Measurement Standards - Fuel Specification Subcommittee has proposed Hydrogen Fuel Method of Sale based on the basis of the kilogram unit of measurement in commercial sales and on street signs. If implemented, the U.S. approach would be consistent with the global hydrogen marketplace in terms of the method of sale.
4. NIST will continue to exchange views and information with the Government of Japan and, as appropriate and where possible, work with the Government of Japan on individual issues.

B. Weight Limits for Containers

1. The Department of Transportation's Federal Highway Administration (FHWA) has explained to representatives of the Government of Japan that 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). Many states have chosen to exercise this option. Should State policy allow 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. The FHWA has furthermore explained that 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, continue to be the permitting authority for overweight movements. The FHWA has been, and will

continue to, work with the states as appropriate to develop regional permits that could facilitate commercial moves between the ports and the end destination.

2. The Government of the United States will continue to work on a regional basis to accommodate increased productivity on permit issuance. FHWA's Commercial Vehicle Size and Weight Team will also continue to work with the Government of Japan on federal weight limits and discuss related issues.
- C. **Equivalence Determination on Organic Crop Products:** On May 19, 2008, the Government of the United States presented a letter to the Government of Japan officially announcing the completion of its positive assessment of Japan's application for an organic recognition agreement. The Governments agreed to continue their work to complete an on site audit, the next step in the recognition process for Japanese organic plant and processed products. Both the Governments of the United States and Japan also agreed to continue their work to explore the possibility for determining equivalence between the Organic JAS system and the U.S. National Organic Program.
- D. **Mitigation of Export Quarantine Requirements for Japanese-Produced Unshu Orange:** The Government of the United States notes that Japan has requested that the citrus canker quarantine conditions for Japanese Unshu oranges be reduced so that the same level protection ensured by the current phytosanitary measures for citrus produced in Florida will apply for Japanese Unshu oranges. The Government of the United States had received information provided by the Government of Japan on March 31, 2008, for the reevaluation of the Japan Unshu orange pest risk analysis, and is currently reviewing that information and technical materials received to reevaluate the pest risk analysis according to U.S. regulations.
- E. **Measures against Bovine Spongiform Encephalopathy (feed regulation, surveillance):** The Government of the United States is working with the Government of Japan towards science-based solutions for these issues.

IX. STANDARDIZATION OF STATE-BASED REGULATIONS (INCLUDING INSURANCE MEASURES)

A. Environmental Regulations

1. The U.S. Environmental Protection Agency (EPA) notes the concerns of the Government of Japan regarding harmonization of environmental regulations on industrial products.
- 2.. As with most federal environmental legislation, the U.S. Environmental Protection Agency (EPA) encourages states to develop their own solid and hazardous waste programs as an alternative to direct EPA management. States can create different waste standards, but these standards must be equivalent to the federal regulations (i.e., they must provide equivalent protection, cannot regulate fewer handlers, etc.).

3. There is no federal-level labeling requirement for products that contain mercury. A number of states, however, have implemented labeling requirements or have proposed legislation that would mandate labeling. EPA will provide the Government of Japan with information on these various state-level requirements.
4. EPA encourages the sharing of best practices on mercury management, and to this end participates in the Quicksilver Caucus, which was formed in May 2001 by a coalition of state environmental association leaders to collaboratively develop holistic approaches for reducing mercury in the environment. The Caucus members share mercury-related technical and policy information with a long-term goal of having State, Federal, and International actions result in net mercury reductions to the environment.
5. EPA is aware of the challenges caused by the growing patchwork of state e-waste laws in the United States, many of which have similar elements. Such elements include manufacturer registration requirements, brand responsibility determinations, return and market share calculations, and manufacturer reports. EPA is in preliminary discussions with several organizations about creating a forum where states with existing electronics recycling laws can share information on common issues and develop strategies that might help ease the financial and compliance burdens on both the states and the regulated community.

B. 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 working toward a national examination program for construction licenses. Providers have begun to develop the NASCLA examination in anticipation of states requesting to use it to meet one of their licensing requirements. NASCLA is considering plans to expand the program to additional examinations. Since September 2007, the NASCLA Examination Program database is in operation, which will speed up the licensing process and help facilitate the sharing of information between states. The Government of the United States will continue to provide the Government of Japan with relevant information on this issue, as appropriate.

C. Harmonization of State-Based Insurance Regulations

1. The Government of the United States is aware that the Government of Japan has highlighted its continued interest in initiatives relating to a federal regulatory system. The introduction of federal insurance regulations continues to be discussed in both houses of Congress of the United States.
2. The Government of the United States, through the Department of Treasury, has also prepared a series of recommendations to reform the U.S. financial regulatory structure. The Blueprint for a Modernized Financial Regulatory Structure

(Blueprint) is a report that provides for a series of short, intermediate, and long-term recommendations for reform of the U.S. financial regulatory structure. Among the various regulatory issues examined, the Blueprint offers several recommendations to address state-based regulatory systems for insurance. Through the Blueprint, Treasury recommends the establishment of a federal insurance regulatory structure to provide for the creation of an Optional Federal Charter; an Office of National Insurance within Treasury would oversee this federal regulatory structure. Treasury also recommends that, as an intermediate step, Congress establish an Office of Insurance Oversight within Treasury to establish a federal presence in insurance for international and regulatory issues.

3. The National Association of Insurance Commissioners (NAIC) recognizes the benefits of harmonization of licensing and regulatory process. Efforts by the NAIC to harmonize state practices and streamline regulatory standards and processes for insurance products continue to advance. The Interstate Insurance Compact (Compact) is a key state-based regulatory modernization initiative that enhances the efficiency and effectiveness of the way asset-based insurance products (such as life insurance) are filed, reviewed and approved in the United States. The Compact's new streamlined processes provide speed-to-market for the insurance industry by promoting uniformity through application of national product standards embedded with strong consumer protections. The Compact became operational in June 2007 and as of May 2008, 30 state legislatures and Puerto Rico have adopted the Compact.

D. Reinsurance Collateral Requirement

1. The Government of the United States notes the continued concerns raised by the Government of Japan regarding reinsurance collateral requirements. The Government of the United States is also aware that the Government of Japan noted how certain States have started to reform their reinsurance collateral requirements. The Government of the United States will continue to ensure that its reinsurance collateral requirements are consistent with its WTO commitments.
2. The Department of Treasury recommended in its Blueprint that Congress establish an Office of Insurance Oversight within the Department of Treasury to address international regulatory issues, such as reinsurance collateral. The Government of the United States will update the Government of Japan on future developments related to the Blueprint and reinsurance.

- E. Trusteed Surplus Requirement:** The Government of the United States notes the concerns of the Government of Japan regarding trusteed surplus requirements. The NAIC has met with the General Insurance Association of Japan to discuss this issue and formed an informal group to further research the issue. The Government of the United States will facilitate communications, as appropriate, between the NAIC and the Government of Japan on trusteed surplus requirements.

X. EXTRATERRITORIAL APPLICATION

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

B. Cuban Liberty and Solidarity Act of 1996

1. The Government of the United States understands the concerns of the Government of Japan regarding the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 (Public Law 104-114). As noted by the Government of Japan, since the enactment of the Act the President has, every six months, suspended the right to bring an action under Title III (which provides for civil suits against persons who traffic in expropriated property), based on findings that such suspension is necessary to the national interests of the United States and will expedite a transition to democracy in Cuba. The duration of the suspension is fixed by statute and cannot exceed six months at a time (P.L. 104-114, Sec. 306).
2. Most recently, on January 16, 2008, the President sent a letter to Congress consistent with the Act to suspend for six months beyond February 1, 2008, the right to bring an action under Title III of the Act.

C. **Sanctions Acts Instituted by Local Governments:** 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 takes sanctions measures by state and local governments seriously and reviews them closely. The Government of the United States will continue those efforts as appropriate, taking into full account its international obligations and policy concerns.

XI. COMPETITION POLICY

A. The federal antitrust agencies of the United States continue to look for opportunities to express their views on the appropriate scope of exemptions and immunities from the application of the federal antitrust laws with a view to promoting competition for the

benefit of U.S. consumers.

- B. In this regard, on October 18, 2007, the Federal Trade Commission (FTC) testified before, and submitted a written statement to, the Antitrust Task Force of the House Committee on the Judiciary opposing H.R. 971, “The Community Pharmacy Fairness Act of 2007,” a bill that would have created an antitrust exemption to allow independent pharmacies to engage in collective bargaining to secure higher fees and more favorable contract terms from health plans. This is in addition to the U.S. antitrust agencies' advocacy work in which they advise state and federal entities on the potential competitive impact of pending governmental actions, including as concerns proposed exemptions and exceptions. For example, in commenting to Puerto Rican legislators on a proposed initiative to permit collective bargaining earlier this year, the FTC underscored its consistent opposition to legislative proposals to exempt from antitrust scrutiny various categories of health care providers.

XII. LEGAL SYSTEM/LEGAL SERVICES

A. Product Liability Law, Punitive Damages, Jury Trial and Discovery

1. 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.
2. In February 2008, the United States Supreme Court issued its opinion in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), holding that premarket approval by the Food and Drug Administration of Class III medical devices preempts state common-law tort claims that are based on allegations that the device was designed, labeled or manufactured in violation of state common law standards that relate to the safety or effectiveness of the device and that differ from, or are in addition to, requirements imposed by federal law.

B. Legal Services

1. Three states – South Carolina, North Dakota and Delaware – have recently adopted foreign legal consultant rules, bringing the total number of U.S. jurisdictions with foreign legal consultant systems to 29.
 - a. Delaware Supreme Court Rule 55.2 allows any lawyer of a foreign country who is in good standing to become a foreign legal consultant, with no minimum number of years of practice requirement.
 - b. The South Carolina (Rule 424 of the Appellate Court Rules Governing the Practice of Law) and the North Dakota (Rule 4 of the Supreme Court Rules on Admission to Practice) foreign legal consultant systems require that a foreign lawyer has practiced law for five of the previous seven years, but counts such practice wherever obtained, including in third countries.

2. The American Bar Association (ABA) 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 ABA's Model Rule for the Licensing and Practice of Foreign Legal Consultants.

XIII. MARITIME TRANSPORT BUSINESS

A. Merchant Marine Act of 1920 and Reporting Requirements Regarding Japanese Ports

1. The Government of the United States and the Government of Japan exchanged views regarding the Merchant Marine Act of 1920. The Government of the United States took note of the Government of Japan's concerns on this matter, and indicated its own continuing concerns about conditions at Japanese ports.
2. The Government of the United States communicated its interest in receiving information from a variety of sources on conditions at Japanese ports. Such information could enable the Federal Maritime Commission (FMC) to consider terminating its proceeding or modifying the reporting requirements it has placed on U.S. and Japanese flag carriers. For example, the Government of the United States understands that the Government of Japan is considering providing, on a government-to-government basis, a translation of Japanese law changed in 2006 that may be relevant to the FMC's ongoing review of conditions at Japanese ports. The Government of the United States hopes that such a translation will be provided in a timely manner, as this could result in the reduction or elimination of the reporting requirements on Japanese flag vessels.

B. Ocean Shipping Reform Act of 1998 (amendment to Section 19 of the Merchant Marine Act, 1920): The Government of the United States explained to the Government of Japan that the 1998 amendment to section 19 of the Merchant Marine Act, 1920 clarified authority already granted to the Federal Maritime Commission. The Government of the United States noted the Government of Japan's concerns on this issue.

C. Maritime Security Program: The Government of the United States exchanged views with the Government of Japan on this national security program. The Government of the United States reaffirmed its commitment to the keeping the Government of Japan informed of the list of the dedicated vessels and of any other changes of material impact to this program. The Maritime Security Program is transparent and all information is publicly available at the Maritime Administration's website: (<http://www.marad.dot.gov/programs/index.html>).

D. Cargo Preference Measures: The Government of the United States and the Government of Japan exchanged views on Cargo Preference Measures including the law requiring that the transport of Alaskan North Slope crude oil be done on U.S.-flag ships. The Government of the United States took note of the opinion of the Government of Japan

that such measures may distort conditions for free and fair competition in the international maritime market. The Government of the United States explained that the measures affect less than one percent of the United States' total ocean borne foreign trades and have a beneficial impact on the U.S. merchant marine industry by providing an incentive for vessels to remain in the U.S. fleet. With regard to the law requiring the transport of Alaskan North Slope crude oil be on U.S.-flag ships, the Government of the United States explained that the last Alaskan crude oil to be exported was in April 2000. Since that time all Alaskan crude oil production has moved to the U.S. West Coast market for refining and domestic consumption.

XIV. 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.

XV. TELECOMMUNICATIONS

A. Competition in the Navigation Devices Market

1. The Government of the United States will continue a dialogue with the Government of Japan on how the Federal Communications Commission (FCC) enforces Section 629 of the Telecommunications Act with a view to ensuring choice in the market for navigation devices (set-top boxes). In June 2007, the FCC initiated a rulemaking to establish reasonable technical requirements to facilitate a competitive market for the supply of interactive navigation devices, and is currently evaluating proposals set forth in the public record. The cable industry and consumer electronics industry continue to negotiate the specific technical requirements for interactive devices; the FCC will continue to monitor those discussions and will adopt rules to ensure that a competitive market for navigation devices develops.
2. Implementation of DTV Converter Box Program: The National Telecommunications and Information Administration (NTIA) is successfully implementing its Converter Box Coupon Program, distributing over 13 million coupons as of May 2008, which consumers can use to purchase from among 85 competitively-supplied certified devices produced by a number of different manufacturers. NTIA welcomes and relies on the voluntary participation of digital-to-analog converter box manufacturers to ensure the success of the Coupon Program. Manufacturers wishing to participate in the program must submit a notice of intent to NTIA at least three months prior to submitting test results and sample models of converter boxes per the process outlined in the Final Rule, §301.5. NTIA's Final Rule adopts technical specifications and features to which manufacturers must adhere in order for a converter box to be eligible for the Coupon Program.

B. Universal Service: In January 2008, the FCC issued two Notices of Proposed Rulemakings seeking comment on ways to reform the high-cost universal service program, including rules governing the amount of high-cost universal service support provided to eligible telecommunications carriers (ETCs) and comment on whether and how to implement reverse auctions (a form of competitive bidding). In May 2008, the FCC issued rules capping high-cost payments at 2007 levels. This action was a crucial first step toward comprehensive reform of universal service and intercarrier compensation, enabling the FCC to move forward expeditiously on comprehensive reform of both universal service and intercarrier compensation.

C. Open Platform Requirements for Designated Licenses in the 700 MHz Auction and

Open Access to the Internet

1. The United States succeeded in winning significant endorsement of an open platform for mobile wireless devices by market participants in the 700 MHz auction, as evidenced by the record number of bids and revenues generated even with the aggressive build-out and open platform requirements for the “C Block.” Following the FCC’s decision to impose an open platform requirement on the C block, a major mobile carrier made a commitment to open its entire network to devices and applications of consumers’ own choosing.
2. The FCC held two hearings (at Harvard University in Cambridge Massachusetts in February 2008 and Stanford University in Palo Alto, California, in April 2008) at which panels of experts rendered advice and opinions on broadband network management practices and Internet-related issues including with respect to operators’ restrictions on the use of peer-to-peer technologies.

D. Local Content Requirement for Federal Government Loans for Telecommunications

Equipment: The United States Trade Representative (USTR) has the authority to waive the application of buy national requirements imposed as conditions of funding by the Rural Utilities Service for telecommunications projects. This waiver authority may only be exercised where USTR determines that another country provides reciprocal access to U.S. products and services and U.S. suppliers. Recognizing the importance of this issue, the Government of the United States will continue a dialogue on this issue with the Government of Japan, and is also willing to consider such a waiver in the context of multilateral negotiations addressing reciprocal requests.

E. Ensuring Prompt Procedures and Transparency for Export Licenses for Satellites:

As detailed in Section VII. A. (Export Licensing Procedures), on January 22, 2008, President Bush issued an Export Control Directive applicable, *inter alia* to satellites and satellite technology, that will improve the manner in which the U.S. Department of State licenses the export of technical data, and expedite the processing of export license applications for items controlled by the U.S. Munitions List. The Export Control Directive mandates commitment of more resources for adjudication and has already reduced average processing times and the backlog of pending applications. The Department of State will also upgrade the electronic licensing system and establish a more efficient dispute resolution mechanism.

F. Development of Broadband in the United States

1. On June 12, 2008, the FCC released its fifth report of deployment of advanced telecommunications capability (706 Report).
2. The report found that the number of high-speed lines with speeds of over 200 kbps in at least one direction – reached 100.9 million including 27.5 million of ADSL, 34.4 million of cable modem, 1.4 million of fiber and 35.3 million of mobile wireless in June 2007. As of June 2007, only 0.1 percent of zip codes in

the United States reported no high-speed lines, compared to 6.8 percent in December 2003.

G. Promotion of Trade in Telecommunications Equipment

1. The Agreement on Mutual Recognition of Results of Conformity Assessment Procedures between the United States of America and Japan entered into force on January 1, 2008. The Governments of the United States and Japan are making preparations towards implementing the Agreement, including training in technical requirements, as soon as possible.
2. Under the arrangement for the acceptance of results of conformity assessment for information technology (IT) equipment and industrial, scientific and medical (ISM) equipment with respect to Electro-Magnetic Compatibility (EMC), 58 Japanese conformity assessment bodies (CABs) have been recognized by the Federal Communications Commission (FCC) and 19 U.S. CABs have been recognized by the Voluntary Control Council for Interference by Information Technology Equipment (VCCI) by the end of May 2008.

XVI. INFORMATION TECHNOLOGIES (IT)

A. Protection of Copyright and Related Rights

1. The Governments of the United States and Japan agree on the importance of protection for and enforcement of copyrighted works.
2. The Government of the United States recognizes the importance of 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 performances. The Government of the United States will ensure transparency regarding the protection for unfixed live performances.
 - 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.
- e. *Rights of Broadcasting Organizations:* The Government of the United States recognizes the importance of rights of broadcasting organizations, and will continue discussions with the Government of Japan with a view toward enhancing transparency of the rights of broadcasting organizations under U.S. law.

B. Response to Digital Networking

- 1. The Government of the United States recognizes that the efficient exploitation 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 promote the smooth usage of copyrighted works and ensure transparency regarding the protection of these rights.
- 4. The Governments of the United States and Japan share the common issue of copyright infringement associated with continued advancements in digital and network technologies. The Governments of the United States and Japan will exchange appropriate, timely information regarding this issue.

C. Spam

- 1. 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.

2. The Federal Trade Commission (FTC) has engaged in a variety of collaborative and educational efforts to combat spam. Examples of such efforts in the last year include holding a Spam Summit in July 2007 to examine shifts in the nature of spam, and releasing a Spam Summit Report detailing next steps in December 2007. On April 1, 2008, the FTC held A Roundtable Discussion on Phishing Education with approximately 70 stakeholders from industry, government, consumer groups, and academia.
3. The FTC actively has pursued deceptive and unfair spam practices, including 31 enforcement actions targeting violators of the CAN-SPAM Act. The Commission recently settled three cases targeting deceptive spam, obtaining nearly \$4 million in civil penalties against three online advertisers offering “free” gifts that were not free.
4. In January 2008, the FTC obtained an over \$2.5 million judgment for misrepresentations violating the FTC Act as well as various CAN-SPAM violations, including sending commercial email messages that had misleading subject headings and that failed to provide clear and conspicuous notice of the opportunity to decline to receive further spam from the sender, a functioning return email address, and/or the senders’ valid physical postal address.
5. As of April 2008, the Department of Justice (DOJ) has prosecuted three additional spam-related cases, generating one guilty plea with two indictments pending. In 2007, the DOJ successfully prosecuted five spam-related cases, resulting in seven guilty pleas, and three guilty verdicts.
6. The Government of the United States passed the U.S. SAFE WEB Act, which went into effect in December 2006. The Act allows 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.
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. In October 2007, the FTC brought its first case using the international information sharing tools under the US SAFE WEB Act to stop spammers from sending commercial email that contained false from addresses and deceptive subject lines. This case is still pending.
9. The Government of the United States and the Government of Japan intend to work together to improve international enforcement in the fight against illegal spam in view of the enactment of the US SAFEWEB Act in the United States and the

amended Japanese anti-spam laws that would facilitate information sharing with foreign authorities in areas of common concern.

10. The Government of United States and the Government of Japan recognize the importance of cooperating with both public and private sector anti-spam entities. For example, the Government of the United States and the Government of Japan acknowledge the valuable work of the London Action Plan, a global network of anti-spam enforcers and industry stakeholders, and promote continued participation by agencies in both countries that are active members of the network as a mechanism for enhancing international spam enforcement cooperation.
11. The Government of the United States shares a common view with the Government of Japan as regards to promoting information sharing among the agencies responsible for anti-spam enforcement in the two countries in appropriate cases and subject to appropriate safeguards in order to enforce anti-spam laws and take appropriate measures against spam.
12. The Government of the United States will continue to explore and consider measures to combat spam with the Government of Japan.

XVII. MEDICAL DEVICES AND PHARMACEUTICALS

- A. **Regular Meetings with Japanese Companies Operating in the United States:** Japanese companies have equal access with manufacturers from the United States and other countries to meet with U.S. Food and Drug Administration technical experts to discuss their pharmaceutical and medical device applications.
- B. **Facilitation of Simultaneous Global Development:** The U.S. Department of Commerce will continue to encourage U.S. companies to work with Japanese regulators to facilitate simultaneous global development of pharmaceuticals and end the drug lag in Japan.