

**FIFTH REPORT TO THE LEADERS ON THE  
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE  
June 29, 2006**

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

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

Following the exchange of recommendations between both Governments in December 2005, Working Groups established under this Initiative met to discuss reform in key sectors and areas such as intellectual property, distribution, privatization of public entities, information technology, competition policy, trade and investment-related measures, commercial law, telecommunications, consular affairs, and medical devices and pharmaceuticals. A High-Level Officials Group met in March 2006 to advance progress on a range of issues raised under this Initiative. Input was also received from representatives of the private sector to augment discussions on issues being addressed through the Initiative's Government-to-Government discussions. Following the Working Group and High-Level meetings, this Report to the Leaders was prepared to record progress as well as clarify measures to be taken in the future that respond to the two Governments' recommendations.

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

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

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

**I. TELECOMMUNICATIONS**

**A. Promotion of Competition**

1. The Government of Japan has implemented a competition policy in the telecommunications field in line with rapid advances of technology, and has thereby facilitated the development of telecommunications markets where broadband services rank among the fastest, most affordable, and most technologically advanced in the world. In Japan, FTTH service as a proportion of broadband Internet subscriptions has been increasing, as has the average transmission speed of such services. Moreover, the number of subscribers to third generation mobile phones and that of subscribed IP telephony exceeded 48 million and 11 million respectively as of the end of March 2006.
2. The Ministry of Internal Affairs and Communications (MIC) set up the “Study Group on a Framework for Competition Rules to Address Progress in the Move to IP” in October 2005, which has been discussing future competition policies in response to the progress in the transition to IP. Specific issues under discussion include examining how current interconnection and other rules should be revised to promote competition in an environment where the telecommunications network is moving from the Public Switched Telephone Network (PSTN) to IP-based networks including frameworks for calculating PSTN interconnection charges during this transition.
3. In November 2005, MIC assigned spectrum in the 1.7GHz and 2GHz bands for three new mobile communications carriers.
4. In December 2005 and April 2006, MIC solicited public comments on “Changing Environment Surrounding Cellular Telephone Business and Future Policy in Response to Such Changes.” MIC will deliberate upon policy measures within FY 2006 including amendments to the “Guideline Concerning Application of the Telecommunications Business Law and the Radio Law Pertaining to MVNOs (Mobile Virtual Network Operators)” adopted in June 2002.
5. In January 2006, MIC Minister Heizo Takenaka established an experts panel on the future direction of Japan’s telecommunications and broadcasting. The panel released its final report in June 2006. This issue is being discussed in the Council on Economic and Fiscal Policy towards the establishment of “Basic Policies for Economic and Fiscal Management and Structural Reform 2006.”

6. The Government of Japan explained the rationale for the requirements that the government hold a specified percentage of NTT shares, and the limit on foreign holdings of such shares.

**B. Fixed Interconnection**

1. After a public comment procedure and receipt of a report from the Information and Communications Council, MIC revised the Rules for Interconnection Charges in February 2006. Based on these new rules, interconnection rates from April 2006 were established as follows: GC interconnection was set at 5.05 yen per 3 minutes, a decrease of 5.1 percent compared to the last fiscal year; and IC interconnection was set at 6.84 yen per 3 minutes, a decrease of 3.5 percent compared to the last fiscal year.
2. In March 2006, MIC revised ministerial ordinances relating to universal service, after conducting a public comment procedure and considering a report from the Information and Communications Council. In the same month, NTT East and West were designated as Eligible Telecommunications Carriers under this system. Based on the new ordinances, this system (including scope of eligible carriers) will be reviewed within 3 years.
3. The Governments of Japan and the United States reaffirmed their continued intention to maintain any universal service mechanism consistent with WTO Reference Paper commitments.

**C. Mobile Interconnection**

1. The interconnection rate of NTT DoCoMo has been reduced over the last 9 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 2006 that the rate would be revised downward by 2.6% compared to the last fiscal year for interconnection within the same NTT DoCoMo service area, and by 5.6% compared to the last fiscal year for interconnection with a subscriber located in a distant NTT DoCoMo service area.
2. Telecommunications carriers that have installed Category II designated telecommunications facilities (e.g., NTT DoCoMo and KDDI) continue to be obliged to notify MIC of and publicize interconnection tariffs in accordance with the Telecommunications Business Law.
3. If payment for interconnection which is received by telecommunications carriers that have installed Category II designated telecommunications facilities surpass the sum of reasonable costs and reasonable profit under efficient management, the Minister for Internal Affairs and Communications may order a change to be made in these interconnection tariffs, and any carrier and others may submit complaints or other views to the Minister under the Telecommunications Business Law. Additionally, when a consultation between carriers fails to come to an agreement,

any carrier can make use of the existing legal framework such as petitions for an order (*meirei*) or an award (*saitai*) to the Minister, or applications for mediation (*assen*) or arbitration (*chusai*) to the Telecommunications Business Dispute Settlement Commission.

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

1. The Telecommunications Working Group of the Regulatory Reform Initiative held a meeting of government officials and private sector experts and exchanged opinions on resolving interference issues in commercial deployment of high-speed Power Line Communications (PLC) in Japan and Broadband Over Powerline (BPL) in the United States. MIC began holding the “Study Group on High-Speed Power Line Communications” in January 2005 and published the final report of the Study Group in December 2005 after a public comment procedure. The Information and Communications Council is currently deliberating on the limits and the methods of measurement concerning facilities for high-speed PLC.
2. MIC held the “Study Group for Wireless Broadband Promotion” from November 2004 to December 2005. In December 2005, MIC published the final report of the Study Group, including the future prospects for wireless broadband services, and development of specific systems based on those prospects, as well as necessary frequency reallocation and promotion strategies after a public comment procedure. On the basis of this report, MIC consulted with the Information and Communications Council, which began considering technical requirements for broadband mobile wireless access systems using the 2.5GHz band in February 2006. In addition, the Information and Communications Council started deliberations on technical requirements for High-Throughput wireless LAN in March 2006.

#### **E. Promotion of Trade in Telecommunications Equipment**

1. The Governments of Japan and the United States will continue formal negotiations with a view to an early conclusion of a Mutual Recognition Agreement (MRA) relating to conformity assessment of telecommunications equipment.
2. Regarding electromagnetic compatibility (EMC), the Governments of Japan and the United States will continue to work together to develop an arrangement that would permit acceptance of results of conformity assessment for information technology (IT) equipment and industrial, scientific and medical (ISM) equipment conducted by accredited Japanese conformity assessment bodies.
3. The Governments of Japan and the United States discussed “Family Approval” of wireless LAN antennas as a request from the Government of the United States. The Governments of Japan and the United States will continue a dialogue on this

issue, taking into consideration policies Japan has established for compliance with technical regulations and the need to address the growing problem in the Japanese market of non-compliant equipment.

- F. **Network Channel Terminating Equipment (NCTE):** Procedures established in the 1990 Letters on Network Channel Terminating Equipment (NCTE), and revised as per the Third Report to the Leaders, ceased to be applied in and after FY2006, after a public comment procedure. Under Article 23 of the Telecommunications Business Law, carriers providing designated telecommunications services are obligated to disclose the technical requirements of NCTE.

## II. INFORMATION TECHNOLOGIES

- A. **IT and E-Commerce Policymaking:** The various e-Japan Strategies and Programs have effectively promoted the use of IT and e-commerce throughout Japan's economy to benefit individuals, create more efficient e-government, and foster high value-added business activities. Japan will continue to strive to foster a regulatory environment that further promotes the utilization of IT, including e-commerce, and provide, as appropriate, meaningful opportunities for interested parties to contribute to IT policy formulation processes.
1. **New IT Reform Strategy:** The New IT Reform Strategy (Strategy) was adopted by the IT Strategy Headquarters (ITSH) on January 19, 2006, after soliciting public comments and giving due consideration to comments it received. The Government of Japan intends to implement the Strategy in a manner that promotes private sector leadership and innovation in IT and e-commerce. In addition, the Government of Japan considers it important not to unduly constrain private sector innovation or market entry, and will continue its efforts to apply this perspective in implementing the Strategy.
  2. **Private Sector Input:** The Government of Japan acknowledges the importance of seeking private sector input in the development and implementation of IT and e-commerce policies. To help achieve this goal, the Government of Japan will provide appropriate opportunities for interested parties to give input at an early stage in the formulation of IT and e-commerce policies.
  3. **Technology Neutrality:** In the 2005 Report to the Leaders, the Government of Japan shared the view with the Government of the United States that it is generally important to implement laws, regulations, and guidelines related to IT in a manner that strives not to unduly promote, mandate, or favor specific technologies (technology neutrality), in order to provide maximum flexibility and encourage innovation in the private sector. The Government of Japan will continue to apply this perspective. In addition, the Government of Japan will cooperate closely with the private sector in international standards development activities and give consideration to established international standards in the implementation of its IT policies.

4. International Compatibility: The Government of Japan considers it important to foster an environment that further promotes cross-border e-commerce. The Government of Japan will continue to seek to harmonize policies and legal frameworks for e-commerce and related Internet technologies with international practice.
5. Public Comment Procedures: The Government of Japan recognizes the need to ensure that the Revised Administrative Procedure Act effectively provides meaningful opportunities for input into the administrative rulemaking process, including for the IT and e-commerce sectors. This Act contains reform measures, including setting the minimum public comment procedure period at 30 days in principle, and requiring Ministries and Agencies to fully consider all submitted public comments.

**B. Strengthening the Protection of Intellectual Property Rights**

1. Copyright Term Extension: The Government of Japan will continue its deliberations on extending the terms of protection for copyrighted works, in consideration of relevant factors including global trends and the balance between right holders' and users' benefits, and will reach a conclusion of its review of the terms of copyright by the end of FY2007. The Government of Japan recognizes the Government of the United States' concern that the term of protection for sound recordings and all copyrighted works be extended, which the Government of the United States recognizes as a global trend.
2. Statutory Damages: The Government of Japan will continue to consider further measures to strengthen protection of copyright and decrease the burden on right holders, including availability of statutory damages for infringement, and will reach a conclusion of its review in this regard by the end of FY2007.
3. Protection of Digital Content:
  - a. The Government of Japan will continue to make public measures it has taken to forbid copyright infringement in their governmental operations including through the misuse of file-sharing technologies and protect intellectual property, including software and other digital content assets used by the government, such as internal regulations and decrees of the agencies which explicitly state any violations of the Copyright Law or other laws and regulations are subject to disciplinary sanction. The Government of Japan will continue to exchange information on this issue with the Government of the United States.
  - b. In addition to other copyright remedies, the Law concerning the Liability of Internet Service Provider has had some positive results with related guidelines since its enforcement in May 2002. Under the Law and the

guidelines, right-infringing information on the Internet, including digital content piracy, can be deleted upon request through a Credibility Confirmation Organization. There are two ways to deal with right infringement on the Internet, which are: 1) prompt deletion based on the Law concerning the Liability of Internet Service Provider, and 2) deletion based on the contractual relation between the Internet service provider and the sender (alleged infringer of copyright). These measures ensure that deletion of right-infringing information on the Internet is properly conducted. The Government of Japan continues to observe the status of implementation of the Law and to take measures against copyright infringement.

- c. The Governments of Japan and the United States will continue to discuss issues related to online piracy, including examining ways to clarify the scope and application of doctrines of secondary liability for copyright infringement, as well as share judicial decisions and related information from respective territories.
  - d. The Government of Japan has ensured the right of making available to address the infringement of copyrights and neighboring rights in works and phonograms that are uploaded onto peer-to-peer networks. The Government of Japan has ensured that this is in compliance with the WCT and WPPT. In addition, the Government of Japan will continue to make efforts to clarify its interpretation of the scope of the private reproduction exception considering provisions of related international agreements and technological developments.
  - e. The Government of Japan will make efforts to clarify its interpretation of the scope of “temporary copy” protection through appropriate measures and a transparent system.
  - f. The Governments of Japan and the United States will continue to discuss issues related to improving protection for technological protection measures. The Government of Japan is studying “access controls” and will continue to update the Government of the United States in this area.
  - g. The Government of Japan and the United States will continue to discuss issues related to end-user piracy.
4. Book Piracy: The Government of Japan will continue to discuss the issue related to reproduction of books, especially on university campuses, with the Government of the United States, and will also discuss the impact of proposed exceptions to copyright protection on scientific, technical and medical publishing.
5. Appropriate Scope for Education Exception in Copyright Law: The Government of Japan has issued guidelines and presented examples of the “educational

exceptions” of the Copyright Law for educational institutions, teachers, and students to clarify the limitations of the exception under the amended Copyright Law. The Governments of Japan and United States will continue to discuss limitations to the exceptions on this issue.

6. IP Strategic Program and Intellectual Property Policies: The Intellectual Property Strategy Headquarters (IPSH) discussed various policies to realize an IP-based nation and created the Intellectual Property Strategic Program (IPSP) in July 2003. The law provides that the IPSP should be reviewed and revised at least once a year. Consistent with this, IPSH finalized and published the IP Strategic Program 2006 on June 8, 2006.
  - a. When reviewing the IPSP, IPSH will provide an adequate period for the solicitation of public comments, in accordance with the general rules on public comment procedure. In doing so, IPSH will ensure that comments from the Government of the United States and other stakeholders are seriously considered and, as necessary, reflected in the final measures and actions.
  - b. The Government of Japan will also ensure that the Basic Law on Intellectual Property and implementing measures for the IPSP are in compliance with international obligations, standards, and norms, and that IPSH and relevant ministries and agencies will be provided with the necessary support and resources to implement the Basic Law and measures for the IPSP.
  - c. By Cabinet Order, the IPSH provides that when developing IP policies the IPSH Task Forces may call experts or persons concerned, including right holders, to their meetings to hear the opinions when the IPSH deems it necessary.

### C. **Cooperation in Efforts against Counterfeits and Pirated Goods**

1. To combat the serious and growing problem of piracy and counterfeiting, both the Governments of the United States and Japan have implemented new initiatives under their respective domestic IPR programs -- the Strategy Targeting Organized Piracy (STOP) in the United States and the “Intellectual Property Strategic Program 2005” in Japan. Notable new initiatives realized in 2006 include:
  - a. *Strategy Targeting Organized Piracy*: Passage of the “Stop Counterfeiting In Manufactured Goods Act,” establishment of a Global IPR Academy, and expansion of IPR experts abroad.
  - b. *Intellectual Property Strategic Program 2006*: Aiming for an early realization of an international legal framework on preventing proliferation of counterfeits and pirated goods, strengthening the regulations of private



import, etc.; and preventing the sale of counterfeits and pirated goods via internet auctions.

2. In addition to establishing their own initiatives in this area, the Governments of Japan and the United States have been and will continue to closely cooperate on strengthening IPR protection and enforcement. Along with cooperating multilaterally, the two Governments, for example:
  - a. Held bilateral meetings regularly to promote IPR protection and enforcement in Asia Pacific and around the world, and
  - b. Co-sponsored under the APEC Anti-Counterfeiting and Piracy Initiative, model guidelines to reduce trade in counterfeit and pirated goods, to prevent against unauthorized copies, and to prevent the sale of counterfeit and pirated goods over the Internet, which was endorsed at the meeting of APEC Leaders and Ministers for Trade in November 2005 in the Republic of Korea.
3. The Governments of Japan and the United States will continue to cooperate in bilateral, regional, and multilateral fora to promote greater protection for IPR world wide by undertaking further actions on a wide range of initiatives, such as the APEC Anti-Counterfeiting and Piracy Initiative and WTO TRIPS transparency request, among others. The Governments of Japan and the United States will expand cooperation to address IPR problems in China using appropriate tools. In addition, the Governments of Japan and the United States will continue to discuss the idea introduced by Prime Minister Koizumi at the G8 Gleneagles Summit in July 2005 regarding a possible international agreement to address the proliferation of counterfeit and pirated goods.
4. The Governments of Japan and the United States have discussed under the Regulatory Reform Initiative ways to cooperate to combat piracy of digital content.
5. The Governments of Japan and the United States will continue to seek and explore possibilities to cooperate with companies and industry associations to arrange joint conferences or seminars to discuss IPR protection strategies. This would include sharing information on IPR enforcement activities.

#### **D. Promoting Online Security**

1. Privacy: The Act on the Protection of Personal Information (Act) went into effect in April 2005. Based on the Act, which outlines the minimum acceptable parameters for all industrial sectors, the new or revised implementation guidelines are industry-specific. Relevant Ministries and Agencies drafted these guidelines after discussion with respective councils and solicitation of public comments. The Government of Japan is making efforts to ensure the transparent, consistent,

and effective implementation of the Act. In implementing the Act and the guidelines, relevant Ministries and Agencies will maintain close liaison and cooperate with each other. The Government of Japan regards it as essential to ensure transparency, respect voluntary efforts by the private sector, and promote better understanding of the implementation of the Act.

- a. On June 8, 2006, the Cabinet Office, the Financial Services Agency (FSA), the Ministry of Internal Affairs and Communications (MIC), the Ministry of Economy, Trade and Industry (METI), and the Ministry of Health, Labour and Welfare (MHLW) sent their experts to participate in a seminar for U.S. and Japanese enterprises on the Act, which provided participants with a valuable opportunity to better understand its implementation.
  - b. The Government of Japan will make efforts to raise awareness and understanding regarding the Act by utilizing the Internet, holding briefing sessions and other methods. Recognizing the usefulness of information on violations and corrective actions for compliance practices of companies, each relevant Ministry and Agency will, as appropriate, publicly provide such information. The Cabinet Office will compile reports each fiscal year from relevant ministers about the enforcement status of the Act including their exercise of authority, such as collecting reports and providing advice, and publicly announce its summary.
  - c. Each relevant Ministry and Agency will clarify, when necessary, whether the provisions of guidelines are mandatory or voluntary and that voluntary guideline non-compliance will not result in penalties to firms. In this area, METI has included language in its “Guidelines Targeting Economic and Industrial Sectors with Regard to the Law Concerning the Protection of Personal Information” that clarifies mandatory or voluntary provisions.
  - d. As noted in the Basic Policy, the Cabinet Office will examine the implementation status of the Act approximately three years after it fully went into effect and will take necessary measures based on the results. Each relevant Ministry and Agency will review its guidelines based on the current circumstances of each business sector.
2. Online Nuisance, Deceptive Practices, and Fraud: The Governments of the United States and Japan are concerned with spam, phishing, and other forms of online fraud that negatively impact businesses and customers, and interfere with the adoption and smooth functioning of IT and E-Commerce. The Government of Japan has been working on multifaceted anti-spam, anti-phishing, and other related measures in close cooperation with private businesses, which include Internet service providers and mobile operators. The Government of Japan will further promote activities aimed at addressing online nuisance and fraudulent practices. As online nuisance and fraudulent practices including spam and

phishing are global in nature, the Government of Japan will strengthen cooperation with the Government of the United States through continued exchange of information, taking advantage of the frameworks of international organizations such as OECD and APEC as well as bilateral consultations.

- a. The Government of Japan promotes measures that include industry-led technological solutions and consumer education to address spam, phishing, and other online fraud in close cooperation with the private sector. MIC, together with private businesses that include telecommunications carriers, has periodically convened the Anti-Phishing Working Group since January 2005 in order to share available information. The Council of Anti-Phishing Japan was established by the private sector under the proposal of METI in April 2005 to promote activities such as the collection and provision of information as well as an awareness campaign.
  - b. The Government of Japan is vigorously enforcing its Law on Regulation of Transmission of Specified Electronic Mail (the Anti-Spam Law), which it has amended to prohibit transmissions disguising information such as senders' addresses, and to include direct penalties for violations of such prohibited acts.
  - c. MIC is promoting understanding of technological measures against spam, through such activities as delivering lectures at seminars hosted by the private sector. MIC is also helping increase private sector understanding of how the Constitutional Secrecy of Communications provisions and the Telecommunications Business Law impact the way technological firms and Internet service providers can develop and use new technologies to filter and block spam in Japan.
  - d. The Governments of the United States and Japan cooperated to hold a U.S.-Japan Financial Technology Seminar in April 2006 to raise awareness, highlight best practices, and promote public-private partnerships to counter online hazards. The seminar was attended by many interested parties, including U.S. and Japanese companies.
  - e. The Governments of the United States and Japan will continue to share information and experiences to improve best practices regarding spam, phishing, and online fraud.
3. Government Information Security: The Government of Japan is continuing its efforts to raise the level of information security in Japan, both in the government and private sector. The National Information Security Center (NISC), established in April 2005, has a lead role in providing guidance, encouraging collaboration among government bodies, and working in partnership with the private sector to address this task.

- a. The Information Security Policy Council (ISPC) decided and released the first overall version of “The Standards for Information Security Measures for the Central Government Computer Systems (‘Standards for Measures’)” on December 13, 2005, after NISC solicited public comments on its draft for 30 days and carefully assessed the feedback received. In addition, NISC publicized the comments received and its view on those comments on its website (www.nisc.go.jp).
- b. The Government of Japan believes it is important to obtain public input as widely as possible when the Standards for Measures are changed in substance. All ministries are required to implement minimum information security requirements in accordance with the Standards for Measures. NISC plans to assess the implementation by each ministry through a cycle of “Plan Do Check Act,” which includes the introduction, evaluation, and review of the Standards for Measures.
- c. In December 2005, ISPC conducted a 30-day public comment period for the draft of its First National Strategy on Information Security. ISPC decided and released the final version of the document in February 2006.
- d. The Ministry of Internal Affairs and Communications (MIC) will revise “The Guideline for Information Security Policy for Local Governments” by September 2006, reflecting the characteristics of each local government in the guideline.
- e. The Governments of Japan and the United States will exchange information and experiences, as appropriate, to improve both countries’ efforts to secure their government information systems.

**E. IT-Related Financial Reforms, e-Medicine, and e-Accessibility**

1. IT-Related Financial Reforms: In the Program for Further Financial Reform, which was established and published by the Financial Services Agency (FSA) at the end of 2004, the FSA is seeking to promote the strategic use of IT to strengthen the competitiveness of Japan’s financial institutions and further develop financial infrastructure. The Program for Further Financial Reform presents “consideration towards establishing legislation for electronic settlements and electronic financial transactions” as one of the measures to create an environment which enables financial services providers to provide diversified financial services with good quality in response to needs of users.
  - a. The FSA affirms the private sector’s lead role in promoting IT investments in financial services through the development and deployment of innovative technologies.

- b. The FSA intends to support the financial sector in undertaking IT investments by collecting and publicly announcing information and statistics on the status of the sector's IT utilization. As part of this process, the FSA surveyed the status of IT utilization by all deposit-handling financial institutions, securities firms, and insurance companies in Japan in summer 2005 and issued survey results in September 2005. The FSA will conduct the "IT Caravan" in FY2006 to provide financial services firms opportunities to share such information.
  - c. The FSA established the Working Group concerning IT Renovation and the Financial System under the Financial System Council last April. In this working group, experts from various fields, including legal experts in the Civil and Commercial Laws, financial experts in the academic field, financial business players and IT experts, deliberate on electronic receivables and new electronic settlement services such as e-cash and publish their discussion points after each deliberation.
  - d. The FSA is working closely with the IT Strategic Headquarters, the Ministry of Economy, Trade and Industry (METI), Ministry of Justice (MOJ) and other relevant ministries to exchange information and promote consistency among Japan's IT-related financial reforms and Japan's other IT and e-commerce regulations and policies, so as to provide predictability to the private sector.
2. e-Medicine: The Government of Japan is promoting the use of IT to enhance the quality, safety, and efficiency of Japan's medical care system. It is also working to formulate and implement measures designed to help Japan rapidly introduce IT solutions for items such as personal medical records and processing of receipts.
- a. MHLW proposed in the May 2005 Final Report of the Consultation Committee on a Standard Electronic Medical Record System, that HL7, an international standard for medical information exchange, should be implemented as a message exchange standard. While it is sometimes inevitable to employ specific technologies under limited circumstances, the Government of Japan will continue its efforts to maintain technology neutrality to the extent appropriate and practicable in the field of e-medicine.
  - b. Through its amendment on April 10, 2006, of the Ministerial Order Regarding the Demands for Payment for Medical Treatment Benefits, Medical Care for the Elderly and Government-subsidized Medical Services, MHLW has directed that all medical receipts, in principle, be submitted online from the beginning of FY2011.
3. e-Accessibility: The Governments of Japan and the United States will continue to exchange information on their respective work and priorities in the area of e-

accessibility, as appropriate, in an effort to better coordinate and enhance understanding of approaches to e-accessibility in both countries.

**F. Promoting Procurement Reforms for Information Systems**

1. Promoting Implementation of Reforms: In January 2006, the Inter-Ministerial Task Force for Information Systems Procurement (Task Force) posted on the Internet the results of a “follow-up survey” (Survey) of progress made by Ministries in FY2004 in implementing the reforms outlined in the Task Force memorandum of agreement. These results indicated that progress has been made in a number of areas, although some areas remain where work to implement reforms continues. The Task Force will continue to monitor the Ministries’ efforts to implement the memorandum’s reforms and urge them to complete this process without delay.
  - a. The Survey showed that the Cabinet Office has adopted measures that increase the flexibility of qualifications for entry into competitive bidding on IT procurement projects, and that nine Ministries have taken steps to promote IT procurements from small and medium-sized enterprises. The Task Force will instruct Ministries that have not yet implemented reforms in these areas to accelerate their efforts to do so.
  - b. The Survey also showed that in FY2004, five Ministries took steps to more clearly define and limit liability in 13 of their IT procurement contracts. In accordance with the Task Force memorandum, these and all other Ministries will steadily take similar steps to clearly define and set appropriate limits on responsibilities for liability between the government and vendors in all future IT procurement contracts.
  - c. As stated in its Intellectual Property Strategic Program 2006, the Government of Japan is preparing to submit legislation to the Diet in FY2007. This legislation will expand the scope of Japan’s Bayh-Dole system by making it possible for contractors to possess ownership rights to intellectual property created through government-sponsored development of information systems, including software.
  - d. MIC will continue to provide, and explore ways to enhance, training for procurement officers of all ministries on IP issues related to government procurement in order to improve their expertise in this area. This will include efforts to encourage procurement officers to allow vendors to take steps to protect their preexisting IPR or that of third parties.
  - e. All Ministries have finished setting rules for investigations of extremely low-priced bids, which will enhance their efforts to promote open and fair competition in IT procurements.

- f. The Government of Japan will continue to work to ensure that its online database for information systems procurement (<http://cyoutatujirei.e-gov.go.jp>) is an effective tool to enhance transparency and fairness in IT procurement. To help accomplish this, the Task Force will:
  - (1) Enhance its outreach efforts to the Ministries to ensure they are fully aware of the database's purpose and functions, and urge all Ministries to contribute all necessary information about their procurement cases to the database without delay; and
  - (2) Analyze information in the database and publish results to help identify trends in information systems procurement, such as changes in the ratio of competitive versus negotiated contracts, use of multi-year contracts, and adoption of bid evaluation methods such as life-cycle cost and Overall Greatest Value Method (OGVM).
2. Improving Procurement Processes: To further improve procurement processes for government information systems, Ministries acknowledge that contracts should be signed as soon as possible after winning bidders are chosen.

### III. MEDICAL DEVICES AND PHARMACEUTICALS

A. **Changes in Japan's Healthcare System:** As the Ministry of Health, Labour and Welfare (MHLW) considers and implements changes in its healthcare system, industry, including U.S. industry, may express its views to MHLW and the Central Social Insurance Medical Council (*Chuikyo*) if the subjects are related to the reimbursement system of pharmaceuticals and medical devices.

#### B. Medical Device and Pharmaceutical Pricing Reform and Related Issues

1. Reimbursement Pricing System Changes: MHLW will consider the value of innovation, the important role of the market, and the need for timely provision of advanced devices and pharmaceuticals to patients when changes to its reimbursement pricing systems for medical devices and pharmaceuticals are implemented.

MHLW will continue to ensure the transparency of the reimbursement price-setting process for medical devices and pharmaceuticals. MHLW will continue to provide industry, including U.S. industry, with opportunities to submit opinions and engage in consultations prior to changes in pricing rules, and with opportunities to express its views at *Chuikyo*. In addition, MHLW will continue to provide industry, including U.S. industry, with opportunities to submit opinions regarding new proposals related to the pricing system of pharmaceuticals.

MHLW will 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.

MHLW will take the following steps, recognizing the value of innovative medical devices, pharmaceuticals, and blood products in FY2006:

a. *Pharmaceuticals:*

- (1) **Premiums:** To ensure that innovative new pharmaceuticals are priced appropriately, MHLW relaxed the requirements for Usefulness Premium (I) so that a pharmaceutical that has a clinically useful and novel mode of action and improves the therapeutic method for the target illness or injury also can qualify for this premium. MHLW raised the premium rates of the Innovation Premium, Usefulness Premium (I), and Usefulness Premium (II) on April 1, 2006, as follows: from 40%-100% to 50%-100% for the Innovation Premium, from 15%-30% to 25%-40% for the Usefulness Premium (I), and from 5%-10% to 5%-20% for the Usefulness Premium (II). On April 1, 2006, MHLW raised the standard amounts in the priority allocation of adjustment premiums as follows: from 300 yen to 500 yen for oral pharmaceuticals, from 1,500 yen to 4,000 yen for injected pharmaceuticals, and from 300 yen to 500 yen for external pharmaceuticals. On April 1, 2006, MHLW also introduced a new premium for pediatric pharmaceuticals with a premium range of 3%-10%. MHLW will apply premiums to innovative pharmaceuticals when such products are introduced and satisfy the requirements of premiums, and will consider using the range of premiums available.
- (2) **Foreign Price Adjustment (FPA) Rule for Pharmaceuticals:** In FY2006, MHLW changed the way it applies the FPA rule for pharmaceuticals. When implementing the rule, MHLW will ask for *Chuikyo*'s consent as appropriate. MHLW exchanged views with industry in FY2005 on implementation of pricing rule changes for pharmaceuticals such as the FPA rule and will continue to exchange views on these issues.
- (3) **Drug Pricing Organization (DPO) Meetings:** On April 1, 2006, MHLW began to officially provide those pharmaceutical pricing applicants who seek an adjustment premium or a price computed by the cost calculation method with opportunities to directly



express their views at initial Drug Pricing Organization (DPO) meetings based on documents they submit before the reimbursement prices of new pharmaceuticals are decided by the DPO. These meetings will increase transparency by enabling the DPO to seek clarification from manufacturers directly and at an early stage in the reimbursement price-setting process.

b. *Medical Devices:*

- (1) **Medical Device Pricing:** During the process of the FY2006 changes in the reimbursement pricing system for medical devices, MHLW consulted fully with industry, including U.S. industry, regarding the method used to collect foreign prices of medical devices. MHLW provided industry, including U.S. industry, with opportunities to express views at *Chuikyo*, and *Chuikyo* discussed these views. MHLW used only data supplied by industry, including U.S. industry, in recalculating the prices of medical devices and retained the maximum percentage in the range of possible reductions. MHLW will continue to consult with industry regarding adjustments to the reimbursement system for medical devices. MHLW will follow *Chuikyo's* recommendation to study the impact of Japan's regulatory and distribution systems on the cost of medical devices in Japan. MHLW also will review industry studies, including the U.S. industry's study, on the cost of doing business in Japan's medical device sector.
- (2) **Foreign Average Price Rule for Medical Devices:** According to *Chuikyo's* basic policy, MHLW will consider measures related to the Foreign Average Price (FAP) rule for devices. MHLW notes that the U.S. Government requested that MHLW eliminate the FAP rule for medical devices before the next price revision and use a new reimbursement mechanism based on market factors in Japan. While the FAP rule remains in effect, MHLW will continue to consult with industry, including U.S. industry, on price data collection.
- (3) **C1 and C2 Pricing:** With regard to medical devices classified as C2, in FY2006 MHLW increased the frequency of health insurance listings to four times a year and already decided to list one device as C2 in April 2006. MHLW will continue to provide C1 classifications and premiums properly and expeditiously. MHLW will continue to respond to questions from industry, including U.S. industry, to clarify the criteria for C1 eligibility and premiums. MHLW will continue to provide information to industry on the products that were awarded a C1 designation.

2. Diagnostics: MHLW will continue to recognize the clinical value of diagnostics (including in-vitro diagnostic reagents [IVDs] and imaging equipment). MHLW is ready to have a dialogue with industry, including U.S. industry, on the categories of individual product tests that are considered to have added clinical value. In the April 1, 2006, reimbursement price revisions for diagnostic imaging equipment, MHLW recognized the differences in quality between conventional and innovative products by granting premiums to innovative products. MHLW will continue to provide reimbursement to advanced in-vitro diagnostic reagents properly and expeditiously.
3. Data Exclusivity: As part of the “Intellectual Property Strategic Program” determined by the Intellectual Property Policy Headquarters, the Government of Japan is examining the idea of an eight-year protection period for test data on pharmaceuticals. To offer greater incentives for the development of new pharmaceuticals, MHLW will continue to study the matter while continuously exchanging opinions with industry, including U.S. industry.
4. Blood Products: On April 1, 2006, MHLW did not reduce prices for most blood products to recognize the costs of implementation of the amended Pharmaceutical Affairs Law (PAL). MHLW will continue to consult with the blood products industry, including U.S. industry, regarding the pricing system.

**C. Medical Device and Pharmaceutical Regulatory Reform and Related Issues**

1. PMDA Resources: In FY2006, MHLW and the Pharmaceuticals and Medical Devices Agency (PMDA) will increase efforts to speed the introduction of safe, effective, and innovative medical devices and pharmaceuticals, and MHLW will ensure PMDA has the necessary resources to meet its performance goals. MHLW will ensure that PMDA has greater resources and expertise by, among other things, employing appropriate personnel to promote the organization’s ability to conduct pharmaceutical and device reviews and provide safety assurance. MHLW will ensure that PMDA accomplishes its goal of expanding its staff size to 346 by March 31, 2009. MHLW will ensure that PMDA provides its examiners with training opportunities and helps its examiners to gain deeper knowledge in their specialized areas through its personnel policies. In FY2005, PMDA provided examiners with several appropriate training opportunities.
2. Pharmaceutical Performance Metrics: PMDA announces at appropriate times statistics on the amount of time the agency takes to complete each step of reviews of New Drug Applications (NDAs) and the number of applications processed. MHLW will ensure PMDA uses performance metrics to facilitate its reviews. PMDA’s report for April-December 2005 included metrics on time from NDA submission to initial interview, time from initial interview to expert review, time from expert review to notification of review results, and time from notification of review results to approval. PMDA will publish these metrics every six months in terms of “administrative time” -- the time PMDA takes to review an NDA. In 2006, PMDA provided industry with additional metrics including those that

differentiate review times for standard NDAs and priority review applications. MHLW will encourage PMDA to continue its dialogue with industry on metrics.

3. Pharmaceutical Application Backlog: MHLW will encourage PMDA to eliminate the backlog of pharmaceutical applications by September 2006.
4. Enhancement of Reviewers' Expertise: In FY2006, MHLW will encourage PMDA to consider ways to enhance its ability to hire qualified pharmaceutical reviewers.
5. Pharmaceutical Clinical Trials: MHLW and PMDA will facilitate conducting pharmaceutical clinical trials in Japan to help attain simultaneous global development. MHLW and PMDA will continue discussion with industry about ways to facilitate simultaneous global development. MHLW will provide U.S. industry with meaningful opportunities to discuss clinical trials, particularly in MHLW's Subcommittee on Clinical Trials.
6. Pharmaceutical Consultations: In addition to face-to-face consultations on pharmaceutical clinical trials, PMDA began conducting paper consultations on a trial basis in April 2006, according to its March 7 Notification. PMDA also began providing concise minutes of the consultations in April 2006. PMDA will review and further improve pharmaceutical consultation practices and strive to reduce waiting times between consultation requests and consultations.
7. Improvements of Medical Device Reviews: In FY2006, MHLW and PMDA will work with industry to improve medical device applications and reviews and will continue to participate in workshops with domestic and foreign industry to help achieve that goal. MHLW and PMDA will take the following steps in FY2006:
  - a. *Partial Changes*: MHLW will require manufacturers to seek PMDA approval of partial changes in medical devices only when such changes are not minor. MHLW and PMDA will inform manufacturers of additional concrete examples to help applicants to understand when they need to seek approval for partial changes. MHLW and PMDA will investigate a number of concrete examples in cooperation with the industry to establish a system whereby applications for partial change approval may be submitted while previous partial change applications already are under review.
  - b. *Medical Device Reviewers*: MHLW will ensure PMDA attains its midterm goals of increasing medical device reviewers and ensuring they are experts in their areas of responsibility. PMDA hired four additional medical device reviewers on April 1, 2006.
  - c. *Backlog of Device Applications*: MHLW will ensure that PMDA eliminates the backlog accumulated prior to the establishment of PMDA,

and brings the volume of new medical device applications waiting for review to a normal level by the end of September 2006.

8. Clinical Trials for Medical Devices: On March 31, 2006, MHLW issued a notification explaining that Japan accepts studies performed according to Good Clinical Practices (GCPs) that are equivalent or superior to Japan's GCPs. PMDA will continue to refrain from requiring that clinical trials be conducted in Japan when relevant evidence gathered outside Japan is available. MHLW and PMDA will inform U.S. and European medical device manufacturers that foreign clinical data is actively used and accepted in Japan. PMDA will continue to provide a scientific and statistical rationale to applicants explaining a decision to require supplemental Japanese clinical data. In the first half of FY2005, Japan approved 20 medical device applications based only on foreign clinical data among 28 medical devices in total. MHLW and PMDA will clarify the criteria of the clinical data required and will accept the minimum necessary clinical data to prove a device's safety and effectiveness.
9. Quality Systems for Medical Devices: MHLW and PMDA will clarify to industry, including U.S. industry, the applicability of quality system audits to suppliers and sterilizers. When conducting quality system audits, PMDA will make efforts to minimize the burden on suppliers and sterilizers.
10. Raw Material Data for Medical Devices: MHLW ensures that PMDA will require manufacturers to provide information on raw materials only when information on the biological safety of a finished product is not adequate to determine the product's safety. In 2003, MHLW issued a notice announcing it would evaluate biocompatibility based on ISO 10993, the international standard for biocompatibility testing. MHLW ensures that PMDA will not request data on biocompatibility testing other than those covered by the ISO 10993 series if the applicant provides PMDA with the scientific rationale for its selection of a particular test method.
11. Accelerated Aging Testing for Medical Devices: MHLW and PMDA will continue to accept accelerated aging testing at the time a medical device manufacturer applies for product approval and not require real-time data until the last stage of the review. MHLW and PMDA will discuss this issue with industry, including U.S. industry, in FY2006.
12. Updating Medical Device Shonin: To lessen the burden on manufacturers and importers of medical devices approved before April 1, 2005, MHLW adopted interim measures after the amended PAL took effect. Taking into consideration views of the parties concerned, MHLW will continue its efforts to ensure a smooth transition into the new regulatory environment under the amended law. MHLW will minimize additional burdens on manufacturers and PMDA resources arising from the reclassification of certain devices under the PAL revision.

D. **Blood Products:** MHLW will treat U.S. blood products companies fairly and transparently by allowing them fair access to marketing and manufacturing opportunities for their entire range of products. MHLW will continue to ensure that implementation of the Supply and Demand Plan for blood products is non-discriminatory against foreign products, transparent, and in full conformity with Japan's international trade obligations. In 2006, MHLW created a working group on manufacturing and supply of albumin and globulin. U.S. industry will continue to have opportunities to take part in the working group as an equal partner with Japanese industry.

E. **Nutritional Supplements**

1. Transparency: MHLW regulates nutritional supplements as one of the categories of foods and will continue to publish regulatory information on foods including nutritional supplements. MHLW will continue to improve the nutritional supplement section of its website and place this information in an easily accessible location.
2. Educational and Informational Statements: With regard to international guidelines and standards for labeling of nutritional supplements, the Government of Japan will continue to play an active role in the development of these documents at the Codex Alimentarius Commission where regulations on health claims are under discussion. In FY2006, MHLW will work with industry to establish a system to provide information from the National Institute of Health and Nutrition (NIHN)'s database to consumers, as recommended by the Office of Trade and Investment Ombudsman (OTO).
3. Import Duties: The Government of Japan will continue to address the issue of tariff levels including on nutritional supplements containing the same ingredients as pharmaceuticals in WTO negotiations comprehensively.

F. **Cosmetics and Quasi-Drugs**

1. Efficacy Claims: MHLW will exchange views with industry, including U.S. industry, on advertising and labeling regulations for cosmetics and quasi-drugs.
2. Transparency: MHLW will continue to improve transparency regarding cosmetics and quasi-drugs regulations.
  - a. MHLW has been providing on its website detailed information on regulatory requirements including new and revised notifications (*tsuchi*), office memos (*jimu renraku*), and registration procedures in a timely manner, in order to give businesses enough time to fully understand them before the regulations go into effect. MHLW will seriously consider ways to make information more easily accessible.

- b. MHLW published its guidelines on advertising for cosmetics and quasi-drugs. MHLW periodically holds meetings with prefectural inspection officials to ensure advertising regulations are consistently enforced. MHLW will exchange views with industry on the advertising regulations stipulated in the PAL and relevant policies.
3. Regulatory Requirements: MHLW has been improving its regulatory requirements with close cooperation with the parties involved including the industry, especially through updating the relevant guidelines and policies in line with scientific advancement. MHLW will exchange views with industry, including U.S. industry, on regulatory issues.
- a. MHLW will work with industry, including U.S. industry, to ensure that product standards are both safe and practical. In fall 2005, MHLW asked the Japan Hygiene Products Industry Association (JHPIA) to review the standard for sanitary pads, and JHPIA will provide its final proposal to MHLW in June 2006. MHLW will review industry's proposal, including deemphasizing the product standard from the Ministerial Ordinance level of regulation to a lower level.
  - b. MHLW will exchange views with industry, including U. S. industry, on ways to facilitate the review process through mutual efforts. When MHLW delegates authority to the prefectures, it is expected that enforcement of regulations, including filing requirements, is consistent across prefectures. MHLW will make efforts to avoid inconsistencies.
  - c. MHLW has been actively participating in the discussions on the Cosmetics Harmonization and International Cooperation (CHIC) program and will continue to do so.

#### **IV. FINANCIAL SERVICES**

##### **A. Specific Measures**

1. Reviewing the Legal Framework of the Money Lending Business: The Financial Services Agency (FSA) Round Table Conference on the Money Lending Business has been reviewing the legal framework of the money lending business since March of 2005 and its chairman's Interim Report (Chairman's Interim Report) was released on April 21, 2006. In considering reviewing the legal framework of the money lending business, the FSA recognizes that it should take into account opinions and proposals mentioned in this report.
- a. By taking account of the ruling parties' discussions of issues on the legal framework of the money lending business, including regulations on lending interest rates, and the recent judgments of the Supreme Court, the FSA will deepen further examination on the appropriate path to be taken to prevent multiple debts of consumers.

- b. The Round Table Conference has reached a general agreement that the “Gray Zone” should be abolished.
  - c. Based on the discussions and the Chairman’s Interim Report, the Government of Japan will continue to consider methods of providing money lenders’ documents to borrowers under the Money Lending Business Law including e-notification, while paying due regard to the necessity of the protection of borrowers.
- 2. Lenders Exchanges and Credit Information: The Chairman’s Interim Report, from the FSA’s Round Table Conference on the Money Lending Business of April 21, 2006, mentions “From the perspective of preventing money lenders’ excess lending to consumers, members of the Round Table Conference generally agreed that there was need for promoting money lenders’ utilization of lenders’ exchanges to raise the accuracy of their credit examination.” The FSA will take into account the opinions and proposals mentioned in the Interim Report and deepen examination on several issues in the money lending business as well as taking the ruling parties’ opinions into account.
- 3. Unifying Regulations on Investment Advisors and Investment Trusts and Measures for Mergers of Investment Trusts: After the amendment of the Securities and Exchange Law and its related laws, which was enacted by the Diet in June of 2006, comes into effect, investment advisors, investment trust management companies and securities companies will be supervised as financial instrument firms under a unified, cross-sectoral regulation, “the Financial Instruments and Exchange Law.” The time of enforcement of this amended law will be designated by the relevant cabinet ordinances. In addition, respecting investor protection, a measure that will enable investment trust managers to merge investment trusts will be introduced if the Law Concerning Investment Trusts and Investment Corporations is amended by the authorization of the “Amendment Bill of Relevant Laws with Enforcement of the Trust Law,” which was submitted to the Diet in March 2006. (Note: This amendment bill was carried over to the next Diet session.)
- 4. Defined Contribution Pensions:
  - a. The Government of Japan recognizes the value of its Defined Contribution (DC) pension system in terms of retirement income security, labor mobility, and investor education.
  - b. The early withdrawal of a small amount of assets became possible in October 2005, in amounts equal to or less than 500,000 yen from personal pension schemes and equal to or less than 15,000 yen from corporate pension schemes.

- c. The Ministry of Health, Labour and Welfare (MHLW) understands the importance of investment advisory services through corporations that run defined contribution pension schemes to their members.
- d. Based on the legal provision, the Government of Japan will consider the necessity of the revision of the Defined Contribution Pension Law, when five years will have passed since its implementation, in October 2006, taking into account input from interested parties. Taking into consideration the implementation of the system to date, MHLW will continuously endeavor to improve the DC pension system.

## B. Transparency

- 1. No Action Letters and General Inquiries Regarding Interpretation of Laws and Regulations: In order to improve further financial administrative transparency and predictability, in 2005, the FSA improved the No-Action Letter (NAL) system to ensure its further convenience and efficiency, and to promote its effective utilization as well as enhancing its supplementary systems. Specifically, the following measures were taken:
  - a. The FSA amended the regulations of the NAL system in response to a survey, covering the general public, on the NAL system conducted in June of 2005. (Survey results were published in October of 2005, and may be found on the FSA website.) The amended regulations reflect the following points:
    - (1) After receiving inquiries, the FSA has to make efforts to respond as soon as possible.
    - (2) Laws and regulations, which the FSA is going to amend in the near future, will be included in the objects of inquiries.
  - b. The FSA published “the List of Reference Cases of Interpretation of Laws and Regulations”, which presented the FSA’s interpretation of its relevant laws and regulations, on its website as one of the supplements of the NAL system. In addition, in April 2005 the FSA also published on its website a procedure for issuing written answers to the general inquiries of interpretation of laws and regulations from financial service providers and relevant associations to which the FSA’s relevant laws and regulations are directly applied.
  - c. The FSA published “the List of Cases of Administrative Orders” on its website in July of 2005. This list shows concrete cases, in which the FSA issued administrative orders, and enables the public to browse their overviews. By being studied by financial institutions and relevant



associations, this list will contribute to prevention of the reoccurrence of the same kind of law violations.

2. Ensuring Transparency of the Legislative Process of “The Financial Instruments and Exchange Law”: To ensure transparency of the legislative process of “The Financial Instruments and Exchange Law,” the FSA undertook the following measures:
  - a. The FSA published the Interim Report of the Financial System Council in July 2005 and solicited public comments. The FSA received more than one hundred opinions on this report from domestic and foreign interested parties, including the American Chamber of Commerce in Japan (ACCJ).
  - b. In addition, in December 2005, the Financial System Council published its report, “The Legislation for the Investment Services Law (*provisional title*),” based on deliberation of its members, market participants and experts.
  - c. Besides such deliberation, the FSA made maximum efforts for ensuring transparency of the legislating process of the Financial Instruments and Exchange Law by having unofficial opportunities for exchanging opinions with representatives of associations related to foreign financial institutions, including the International Bankers Association (IBA), in order to ensure opportunities to receive opinions from both domestic and foreign interested parties.
  - d. The amended Securities and Exchange Law and its related laws, which were drafted based on the report of the council, were enacted in June of 2006. After being enacted, in the process of establishing draft amendments of the relevant cabinet and ministerial ordinances, the FSA will ensure the transparency of this process by publishing drafts of these ordinances through the public comment procedure.
3. Utilization of the Public Comment Procedure: During the process of amendment of various cabinet and ministerial ordinances, the FSA undertakes the public comment procedure to ensure opportunities, in which any person and entity is able to present opinions on the amendment, and publishes its policy as a response to these opinions. In addition, the Amended Administrative Procedure Law, which came into effect in April of 2006, established the public comment process as a statutory procedure by setting its minimum period at 30 days in principle. Based on this amended law, the FSA is making further efforts to ensure financial regulatory transparency by appropriately operating the public comment process.

## V. COMPETITION POLICY

A. **Enhancing the Effectiveness of the Amended Antimonopoly Act (AMA):** The Government of Japan is committed to fostering competitive markets through strong and effective enforcement of the Antimonopoly Act (AMA). In this regard, on March 31, Prime Minister Koizumi announced a new three-year regulatory reform program that includes reviewing and strengthening the Japan Fair Trade Commission's (JFTC) enforcement authority and organization, stepping up enforcement of the AMA and transferring public-sector facilities and services to the private sector. In addition, Japan has taken, or intends to take, the following measures to strengthen its competition policy:

1. Maximizing the Effectiveness of JFTC's Leniency Program: JFTC's new Antimonopoly Leniency Program, which eliminates or reduces the surcharge for the first three enterprises that report the existence of a cartel or bid rigging conspiracy to the JFTC, came into effect on January 4, 2006. In order to maximize the effectiveness of the Leniency Program and to promote active applications to the program, JFTC:
  - a. Published "Rules on Reporting and Submission of Materials Regarding Immunity from or Reduction of Surcharges," together with relevant application forms and instructions for completing those forms;
  - b. Clarified the requirements for leniency applications in "The Fair Trade Commission's View on New Rules of the Amended Antimonopoly Act: Comments Addressed to the Commission Regarding the Draft of its Rules and the Point of View of the Commission," which was published on JFTC's English website on April 11, 2006. In that document, JFTC made clear that in order to ensure that requirements to translate foreign language materials into Japanese do not cause potential leniency applicants to delay submitting their applications, JFTC will allow applicants to submit abridged translations of required materials that evidence a violation of the AMA, and to submit the entire translation at a later date, if requested by JFTC; and
  - c. Took steps to ensure the confidentiality of leniency applications by clarifying that:
    - (1) JFTC's policy is not to disclose to a court or others the contents of a report submitted by leniency applicants, and;
    - (2) Leniency applicants will be permitted to submit an oral, rather than written, report on the details of a violation, etc.
2. Strengthening Deterrence of AMA Violations and Enhanced Compliance with the AMA: In order to strengthen the deterrent effect of the AMA and to promote corporate compliance with the AMA, JFTC:

- a. Published “The Fair Trade Commission’s Policy on Criminal Accusation and Compulsory Investigation of Criminal Cases Regarding Antimonopoly Violations” in October 2005 based on the introduction of criminal investigation powers for JFTC;
    - (1) JFTC will make good use of these new powers against vicious and serious violations, etc., of the AMA, and will actively bring cases and file criminal accusations against companies and individuals engaging in such violations.
    - (2) In this regard, JFTC used its new criminal investigation powers in its investigation of bid rigging on human waste disposal facilities construction projects and filed criminal accusations against 11 companies and 11 persons in May and June 2006.
  - b. Intends to revise its “Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Act.” JFTC will publish the draft by mid-summer and finalize the guidelines after seeking comments from various parties, including the foreign business community and the U.S. Government.
3. Strengthening the Economic Analysis Capabilities of JFTC Staff and Resources: JFTC is steadily increasing its staff and budget. The total number of its staff is expected to reach 737 as of March 31, 2007. Since 2001, JFTC has employed five economists educated in graduate school and has been making good use of their expertise in JFTC’s work. JFTC will continuously improve the analytical capabilities of its staff through training and the accumulation of practical experience, and will strengthen the organization as appropriate.

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

1. Prior Procedures for Cease and Desist Orders and Surcharge Payment Orders: JFTC has introduced the prior procedure system under which JFTC will make an advance notification of a draft cease-and-desist order or surcharge payment order to the proposed recipient of these orders. JFTC will be prepared at that time to explain to the proposed recipient the facts found by JFTC and the basis of calculation of the surcharge amount, and to disclose to the proposed recipient the evidence it obtained that is necessary to prove the violation that would be the basis of the proposed order, upon a request from the proposed recipient. The proposed recipient of such an order will be provided the opportunity to present its views and submit evidence to JFTC before the order is issued. The proposed recipient of the order will, in principle, have approximately two weeks after the advance notification to submit its views and evidence to JFTC. However, in a case where JFTC recognizes that additional time is necessary to provide the explanation to the proposed recipients, it will set a longer period for the proposed

recipient to submit its views and evidence, taking such circumstances into consideration.

2. Prior Procedure in Warning Cases:

- a. With the enactment of the amended AMA in January 2006, JFTC introduced the prior procedure system for the issuance of warnings against suspected violations of the AMA. Specifically, JFTC will deliver a draft of a warning to the proposed recipient and provide the opportunity to submit its views and evidence to JFTC prior to issuance of the warning.
- b. Regarding suspected violation of the Premiums and Representations Act, JFTC has implemented the same prior procedure system as for proposed warnings for suspected violation of the AMA.

3. AMA Basic Issues Study Group:

- a. The office of AMA Basic Issues Study Group continues to disclose the conference materials and the minutes of its meetings on its website.
- b. The Study Group expects to publish an interim report of its work in the summer 2006, and will provide an opportunity for public comment on the interim report, including from interested foreign parties and organizations.

**C. Addressing Bid Rigging Effectively**

1. Administrative Leniency: In light of the AMA amendments establishing the JFTC leniency program, in February 2006, the Ministry of Land, Infrastructure and Transport (MLIT) implemented an administrative leniency policy under which MLIT will reduce by half the period of suspension from bidding for companies that were admitted to JFTC's leniency program with regard to a particular bid rigging conspiracy, provided that MLIT becomes aware of such company's participation in JFTC's leniency program through disclosure by JFTC. The implementation of such an administrative leniency program by other government agencies and public corporations will be decided by each such entity.

2. Administrative Penalties:

- a. In September 2005, MLIT announced a policy of doubling the minimum period of suspension from bidding for companies that commit a second violation of bid rigging within ten years. For example, the minimum period of suspension from bidding for a second serious violation of the AMA was increased from six months to 12 months. This measure was put into force on January 4, 2006, simultaneously with the effective date of the amended AMA.

- b. To prevent recurrence of bid rigging, MLIT implemented a policy in July 2005 to recover damages from companies that participated in bid rigging on construction services contracts in which the JFTC and/or the judicial authorities find bid rigging violations even if the contracts were made before the introduction of the pre-established claim clause in June 2003.
3. Competitive Bidding:
- a. For the purposes of promoting fair competition and eliminating improper conduct, on May 23, 2006, a Cabinet Decision was issued that revised the Guiding Principles concerning Measures to Promote Proper Tendering and Contracting for Public Works. The revisions, which will help prevent bid rigging, include an expansion of the open and competitive bidding procedure, strengthening supervision of bidding, strict implementation of suspension from bidding in cases of improper conduct, and ensured efforts to eliminate and prevent government-led bid rigging.
  - b. MLIT confirms that the location of a company's headquarters or branch offices is not used as a qualification requirement for participation in the open and competitive tendering procedures for public works whose value is more than the threshold of the WTO Agreement on Government Procurement.
4. Conflicts of Interest – Amakudari: In order to secure public trust in public works projects, MLIT has taken the following measures. As part of its July 29, 2005, countermeasures to prevent the recurrence of bid rigging, MLIT requested that:
- a. All MLIT officials refrain from finding reemployment with the companies that participated in the bid rigging on the steel bridge construction projects last year; and
  - b. Senior MLIT officials refrain from finding reemployment for five years after their retirement with any company that had contracts for MLIT construction projects.

## **VI. TRANSPARENCY AND OTHER GOVERNMENT PRACTICES**

### **A. Public Comment Procedure**

- 1. The Government of Japan continues to work to improve the Public Comment Procedure (PCP) to increase transparency and ensure fairness in the administrative rule making process. The Revised Administrative Procedure Act which codifies the legislation of the PCP was enacted on April 1, 2006. This Act contains numerous reform measures to strengthen the PCP, including:

- a. Requiring Ministries and Agencies to make public the draft orders/regulations and related documents by using the Internet and other means as necessary;
  - b. Setting the minimum PCP period at 30 days in principle. In exceptional cases where less than 30 days are provided, Ministries and Agencies must make public the reason for this determination to shorten the period when they make public the draft orders/regulations;
  - c. Requiring Ministries and Agencies to fully consider all submitted public comments; and
  - d. Requiring Ministries and Agencies to make public the complete text and/or summary of the submitted comments, and also indicate how comments were incorporated or not incorporated and the reasons for the decisions.
2. The Government of Japan recognizes the need to ensure that the amended Administrative Procedure Act effectively provides meaningful opportunities for input into the administrative rulemaking process. MIC will continue to conduct and publish comprehensive annual surveys on the Ministries' and Agencies' implementation of the PCP, and will maintain close communications with relevant Ministries and Agencies in this regard.
  3. In addition, the Government of Japan will consider taking necessary measures to ensure the Administrative Procedure Act effectively provides such meaningful opportunities for input.
- B. Foreign Translations of Japanese Laws:** On March 23, 2006, the Government of Japan decided to take necessary measures so that English translations of approximately 200 laws and regulations would be produced in accordance with the Translation Development Program for FY2006-2008, based on the final report made by the "Study Council for Promoting Translation of Japanese Laws and Regulations into Foreign Languages," composed of experts as well as relevant ministries and agencies. And in April 2006, the Government of Japan started providing information on this project on the Cabinet Secretariat's Website. The Government of Japan will make efforts to ensure the secure implementation of the Program and will continue to hear outside opinions and requests in considering revising the Program.
- C. APEC Transparency Standards:** Japan and the United States will continue their joint efforts to encourage APEC member economies to fully implement the APEC Transparency Standards in their domestic legal regimes.
- D. Special Zones for Structural Reform**

1. Prime Minister Koizumi and his Administration continue to make the Special Zones for Structural Reform a priority component of Japan's economic revitalization plan. Since the approval of the first 57 Special Zones in April 2003, the total number of zones has grown to 630 as of March 31, 2006.
2. In order for the positive economic impact of the successful zones to be spread through the greater Japanese economy, the Government of Japan applies successful regulatory exemptions in the Special Zones on a national basis as expeditiously as possible and will operate the entire application and regulatory exemption process for the Special Zones in a transparent manner. The Government of Japan has applied a total of 64 zone measures nationwide as of March 31, 2006. The Government of Japan will continue to nationalize successful regulatory reforms adopted in the zones.
3. The Government of Japan also responds as fully as possible to inquiries made by foreign companies for information on Special Zones. The Government of Japan will continue to ensure the transparency and effectiveness of the zones.

**E. Public Input into Policy Development – Advisory Groups**

1. 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, according to which these groups, for example, publish meeting minutes and endeavor to provide opportunities to hear the opinions of interested parties. Meanwhile, the Government of Japan recognizes the view of the Government of the United States that the transparency of and access to such advisory groups should be enhanced through the establishment of stronger transparency standards governing these groups.
2. Lists of some of the advisory groups and their membership are electronically accessible at 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.

**F. Public Input into the Development of Legislation:** Some Ministries and Agencies, at their discretion, have been opting for public input into draft legislation during its development, before it is submitted to the Diet.

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

1. The amended Insurance Business Law, which came into effect on April 1, 2006, extended the period of existence of the scheme of the Insurance Policyholder Protection Corporation (PPC), including a government guarantee of financial resources as financial assistance in case of an insurance company bankruptcy.

This amended law also stipulates that the system regarding PPC's financial resources will be reviewed within three years after April 1, 2006.

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

#### **H. Bank Sales of Insurance**

1. The Ministerial Ordinance of the Insurance Business Law was amended on July 8, 2005, based on the report of the Second Sub-Committee of the Financial Council, issued on March 31, 2004.
2. This amendment partly lifted the ban on selling insurance products at bank branches on December 22, 2005, and introduced consumer protection safeguards with respect to sales of insurance through banks. After monitoring the effectiveness of these safeguards until December 2007, the Financial Services Agency (FSA) plans to lift the ban on selling any insurance product at banks and will implement related technical preparations prior to full liberalization.
3. In the process of changing the regulation, FSA took into consideration opinions of various interested parties, including domestic and foreign insurance companies and banks, and solicited public comments on the draft amendments of the Cabinet and Ministerial Ordinances of Insurance Business Law.
4. During the process of monitoring insurance solicitation by banks, the FSA will hold regular hearings with insurance companies, banks, and other various interested parties as necessary.
5. 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 or one services supplier over another.

#### **I. Insurance Cooperatives**

1. With regard to unregulated *kyosai*, an amendment to the Insurance Business Law, which came into effect on April 1, 2006, expanded its scope to include unregulated *kyosai* and introduced the Small Amount and Short-Term Insurance Providers (SASTIP) system.
2. During the process of the consideration of this reform, the Financial Services Agency (FSA) consulted with the Financial System Council, exchanged opinions with foreign insurance companies, and published a draft amendment of the relevant ministerial ordinance for public comments.



3. The Amended Insurance Business Law stipulates that FSA will review the SASTIP system within five years from the date of its enforcement. To conduct the review, the FSA will, as necessary, provide information on the review and meaningful opportunities for input from insurance companies, including foreign insurance companies, and other parties concerned.
4. With regard to 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 a review should 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, and that such a review should be undertaken in a transparent manner with opportunities for interested parties to express their views.

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

1. The Government of Japan took meaningful steps in 2005 to adopt a more internationally accepted plant quarantine system based on the International Plant Protection Convention (IPPC) standards for official control and risk analysis.
2. The Government of Japan made significant progress in revising quarantine status and/or inspection practices for four pests identified by the Government of the United States. The Government of Japan will continue to conduct pest risk analyses (PRA) to determine whether the remaining four pests should be subject to quarantine measures.

### **VII. PRIVATIZATION**

#### **A. Privatization of Public Corporations**

1. On December 19, 2001, the Cabinet adopted the “Reorganization and Rationalization Plan for Public Corporations.” In implementing this Program, by the end of March 2006, the Government of Japan conducted necessary measures (amendments of relevant laws, etc.) to organizationally reform 136 of the 163 public corporations subject to the Program.
2. The Government of Japan remains committed to the continued restructuring and privatization of Japan’s public corporations and will continue to undertake this process in a transparent manner, including through active use of Public Comment Procedures and, where appropriate, other measures that will contribute to ensuring transparency.
3. Established by the Government of Japan, an advisory committee consisting of well-informed experts from the private sector to monitor and evaluate the implementation of the Program has met 49 times since its launch in July 2002. The summaries of the minutes of those meetings and discussion papers have been made public.

## B. Japan Post

### 1. Level Playing Field for Postal Savings and Insurance:

- a. The financial information of the Japan Postal Services Holding Company, Postal Service Company, Post Office Company, Postal Savings Bank, and Postal Insurance Company will be disclosed under the same regulations as other private sector companies, including those under the Corporate Code, Banking Law, Insurance Business Law, other related laws and ordinances, and, when engaging in public capital market transactions, the Financial Instruments and Exchange Law (Securities and Exchange Law). The relationships and transactions among the Postal Savings Bank, Postal Insurance Company, Japan Postal Services Holding Company, and Post Office Company will be required to meet the obligations under the Banking Law and Insurance Business Law, including with respect to the arms-length rule. For purposes of accounting regulation under the Banking Law and Insurance Business Law, these four companies will be considered to meet the ‘special relationship’ criteria under the requirements of these laws.
- b. The laws on postal services privatization stipulate no scheme that will make possible ex-post cross-subsidization among the newly established 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 these laws, the objective of the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance shall be to appropriately and in a sound manner manage postal savings and postal life insurance contracts inherited from Japan Post. Japan Post will prepare and disclose its financial statements as of September 30, 2007, after being audited by an independent auditor. The Valuation Committee will value assets and liabilities succeeded to the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance, and this valuation will be completed in accordance with Japanese GAAP. The Government of Japan takes note of the view of the Government of the United States that the timely public disclosure of this valuation is important. Under the Law Concerning the General Rules of Incorporated Administrative Agencies, the Incorporated Administrative Agency Management Organization for Postal Savings and Postal Life Insurance is to prepare and disclose annual financial statements audited by an independent auditor in accordance with Japanese GAAP. The laws stipulate that, from October 2007, the asset management arisen from inherited pre-privatized contracts will be delegated to the Postal Savings Bank and Postal Insurance Company by way of deposit and reinsurance contracts. As of October 2007, these deposit and reinsurance contracts

shall be subject to the Banking Law and Insurance Business Law as well as to Financial Services Agency (FSA) oversight and supervision and thus will be on a commercial basis. The laws further provide that the original deposit and reinsurance contracts will be stipulated in the Business Succession Plan, which will be reviewed by the Postal Services Privatization Committee (PSPC) (a third-party organization comprised of intellectuals) prior to government approval (to take place before October 2007), taking into consideration competitive conditions of the new financial companies with other private financial institutions.

- c. The existing laws governing the privatization of Japan Post allow the Post Office Company to make insurance soliciting contracts with private insurance companies other than the Postal Insurance Company, and to make agency contracts with private banks other than the Postal Savings Bank. In terms of access to the Post Office Company's network, a level playing field is secured between the Postal Saving Bank and other private banks and financial institutions, and between the Postal Insurance Company and other insurance companies respectively.
- d. Beginning October 1, 2007, deposits received by the Postal Savings Bank and the life insurance products sold by the Postal Insurance Company will not be guaranteed by the Government. Efforts are being made to make the public aware that these products will be covered by the Deposit Insurance Corporation of Japan or by the Life Insurance Policyholders Protection Corporation of Japan, and not be guaranteed by the Government from October 1, 2007. Sales of such products after this time that are misrepresented as being guaranteed by the Government are prohibited by the Banking Law and Insurance Business Law.
- e. The Antimonopoly Act and other laws will be applied to the privatized companies on the same basis and according to the same standards as they are applied to any other private company.
- f. 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 the Post Office Company, Postal Service Company, Postal Savings Bank, or Postal Insurance Company. To implement the Regional Contribution Activity, the Post Office Company is obliged to make an implementation plan which is to be approved by the Minister of Internal Affairs and Communications, and to publish the plan without delay after its approval. The company is also obliged to publish a report on how the Activity was implemented within 3 months after the end of the plan's effective period. 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. When providing postal services, the Postal Service Company will continue to be subject to the supervision of the Minister of Internal Affairs and Communications under postal laws and ordinances, and newly should become subject to the supervision the Minister of Land Infrastructure and Transport under freight transportation laws and ordinances in case of using trucks and similar vehicles as well as employing air, sea, or, land transportation provided by other carriers.
- c. The same “duty declaration” system should be applied to customs clearance procedures for international physical distribution services provided by Japan Post or the Postal Service Company as those applied to those for other private companies.
- d. The Government of Japan will continue to consider the matter of customs clearance procedures for postal items including EMS.
- e. Japan Post should disclose the status of profit and loss according to the categories of postal services and international physical distribution services. Also, the Postal Service Company should disclose the status of profit and loss according to the categories of postal services and other services. These disclosures, a measure taken by the Government of Japan, are to be made in a manner that will allow for an objective evaluation of whether cross-subsidization is occurring.
- f. The same taxation system should be applied to the Postal Service Company as applied to other private companies, except for the minimum necessary measures for the smooth transition and succession of business and functions of Japan Post.
- g. Japan Post and, from October 2007, the Postal Service Company shall be subject to the same aviation safety and security laws and regulations as other private companies.

4. Inclusiveness and Transparency:

- a. 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 can appropriately make the opportunities to hear views of interested parties if the Committee considers it necessary. The Office for the Promotion of Privatization of Postal Services, Ministry of Internal Affairs and Communications, and FSA will continue to provide opportunities for private sector interested parties, upon request, to exchange views with relevant officials. While recognizing the independence of the PSPC, the

Government of Japan also recognizes the importance of the transparency of the PSPC.

- b. As is stipulated in the Law of Privatization of Postal Services, the Prime Minister appointed the PSPC Members, and the PSPC was established on April 1, 2006. Under the Standing Order of the PSPC, the PSPC is to in principle make publicly available summaries of meeting minutes as well as detailed meeting minutes in a timely manner. For each of its meetings to date, the PSPC has held post-meeting press briefings and has made publicly available such summary and detailed meeting minutes. The Secretariat of PSPC will make advance notice of the PSPC's agenda publicly available (including on the relevant website) prior to each PSPC meeting.
- c. 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. The Japan Postal Services Holding Company will submit the framework of its implementation plan to the Prime Minister and Minister of Internal Affairs and Communications by July 31, 2006, and will also make this framework publicly available. The Government of Japan recognizes that its publication increases transparency in the Japan Post reform process. The Government of Japan takes note of the view of the Government of the United States that transparency should be further enhanced by opening the implementation plan to a meaningful public comment process before it is finalized.
- d. Issues arising from the implementation of the laws on postal services privatization will also be further addressed in a manner described in the last paragraph of the preface of this Report.

## VIII. LEGAL SYSTEMS REFORM

- A. **Ensuring Freedom of Association of Foreign Lawyers:** The amended Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers (*Gaiben Law*), which lifts the ban on employment of Japanese lawyers (*bengoshi*) by registered foreign lawyers (*gaiben*) and introduces the system of joint enterprises between *bengoshi* and *gaiben* (*gaikokuho kyodo jigyo* or "GKJ"), came into force on April 1, 2005, and has been implemented appropriately so far. The Ministry of Justice (MOJ) will, as necessary, continue to discuss appropriate implementation of the *Gaiben Law* with the Japan Federation of Bar Associations (*Nichibenren*) and with *gaiben* so that the rules and regulations of *Nichibenren* and the local bar associations in that regard are consistent with the views of MOJ.

- B. **Permitting Professional Corporations and Branches:** MOJ has been studying whether (i) *gaiben* should be permitted to form legal professional corporations on the same basis and with the same benefits as *bengoshi* professional corporations, and (ii) foreign law firms and the *gaiben* partners in Japan should be allowed to establish multiple offices staffed in accordance with Japanese law without forming a separate Japanese legal professional corporation, from the standpoint of trends in international legal services and principles of non-discrimination. Since last year MOJ has had several meetings with *Nichibenren* and *gaiben* in order to discuss these issues. MOJ will continue to study these issues in light of the actual operation of GKJ and *bengoshi* professional corporations and consistency with other laws and regulations in Japan. By April 2007 MOJ will inform the Government of the United States of its findings and any conclusions it has reached on these matters.
- C. **Permitting Foreign Lawyers to Participate in Alternative Dispute Resolution Proceedings:** The Government of Japan confirms that *gaiben* can represent parties in ADR proceedings taking place in Japan in which one of the parties is foreign or foreign law is applicable, at least to the extent such representation is not inconsistent with the *Gaiben Law*. The Government of Japan takes note of the views of the Government of the United States that *gaiben* should be permitted to act as neutrals in all forms of ADR proceedings that take place in Japan and will give further study to whether any measures can appropriately be taken to provide greater legal certainty in this area.

## IX. COMMERCIAL LAW

### A. Implement Modern Merger Techniques

1. The provisions of the Corporate Code relating to “flexibility of merger consideration” -- which will permit the use of triangular mergers, cash mergers, and other types of mergers using properties other than shares of surviving companies as consideration, including using foreign shares -- will come into effect as of May 1, 2007. The provisions of the Corporate Code permitting short-form (squeeze out) mergers came into effect as of May 1, 2006.
2. If the Ministry of Justice (MOJ) should determine in the future that the ministerial ordinance regarding the above provisions should be amended, it will publish any proposed amendments, and solicit and consider public comments, including from the foreign legal and business communities, before finalizing such amendments.
3. The Government of Japan, noting that the Government of the United States pointed out that tax considerations are crucial for companies in determining whether to participate in an M&A transaction, is studying tax treatment relating to “flexibility of merger consideration” available under the Corporate Code, taking into consideration the appropriateness and equity of taxation and the prevention of tax avoidance. The Government of Japan will reach a conclusion on the appropriate tax treatment of M&A transactions using these new Corporate Code

provisions, to be reflected in the Tax Code, before the related provisions of the Corporate Code come into effect on May 1, 2007.

**B. Facilitate Efficient Tender Offer Bids**

1. On June 7, 2006, the Diet enacted the Amendment Bill of the Securities and Exchange Law (SEL). The amended SEL enables persons making tender offers to:
  - a. Withdraw the tender offer when the target company (i) splits its stock or allocates stock to other shareholders in a manner or at a price that dilutes the offeror's stock holdings in the target, or issues new stock or subscription rights to other shareholders, or (ii) fails to lift a poison pill or other anti-takeover measures; and
  - b. Modify the tender offer by reducing the offer price to compensate for a stock split, or for an allocation of new shares in a manner or at a price that dilutes the offeror's stock holdings by the target company.
2. The amended SEL also requires target companies to submit to the Commissioner of the Financial Services Agency (FSA) within the period designated by the Cabinet ordinance a public statement of the position of the Board of Directors regarding the tender offer, including the basis for the position and the procedure used to arrive at that position.
  - a. Target companies that submit a public statement with fraudulent information are subject to a maximum fine of five million yen. The executives of such companies are also subject to maximum imprisonment of five years and/or a maximum fine of five million yen.
  - b. Target companies that fail to submit a public statement are subject to a maximum fine of one million yen. The executives of such companies are also subject to maximum imprisonment of one year and/or a maximum fine of one million yen.
  - c. The amended SEL also requires offerors to answer questions posed by the target company within the period specified by Cabinet ordinance.
3. In February 2006 MOJ promulgated implementing regulations for the new Corporate Code amendments. Article 127 of those regulations requires a company to specify in the company's business report (which must be prepared annually and disclosed to its shareholders under the Corporate Code) any anti-takeover measures that it has adopted, as well as an explanation of why such measures do not undermine the interests of the company and its shareholders as a whole and are not motivated by the self-interests of senior officers.



### C. **Protect Foreign Firms Legitimately Doing Business in Japan**

1. The Government of Japan will ensure that Article 821 of the Corporate Code (which deals with quasi-foreign companies) does not adversely affect the operation of foreign companies that are duly registered in Japan and conduct their operations in a lawful manner. The intent of the Diet in this regard was clarified during the deliberation on the Corporate Code bill in the Diet.
2. In furtherance of this goal, in March 2006 MOJ -- after soliciting the views of the foreign business community -- issued an internal notification (*tsutatsu*), which clarifies the interpretation of Article 821 in order to address concerns among foreign companies operating in Japan.
3. At the House of Councilors, an ancillary resolution to the Corporate Code bill was adopted which stipulates that Article 821 will be reviewed, if necessary, taking into consideration any effect on foreign companies caused by Article 821 after the Corporate Code comes into effect. Thus, the Government of Japan will watch closely such effect and positively consider amendment of Article 821 if necessary to prevent adverse effects on the legitimate operation of foreign companies in Japan.

### D. **Strengthen Good Corporate Governance**

1. Promoting Shareholder Value through Active Proxy Voting by Institutional Investors:
  - a. The Government Pension Investment Fund (GPIF) was newly established as an independent administrative organization in April 2006. In recognition of the importance of corporate governance, the Minister of Health, Labour and Welfare issued a medium-term objective to GPIF on April 1, 2006. In accordance with those objectives, GPIF issued its medium-term plan, which stipulates that the exercise of proxy voting rights by fund managers should be undertaken with the aim of maximizing long-term stockholders' interest. The plan also states that GPIF will request reports from its fund managers on their proxy voting policy and on their exercise of proxy voting rights. The summary of the results of proxy voting by all fund managers, based on the policy established by such managers, will be announced publicly in the annual report of GPIF.
  - b. The Government of Japan supports the promotion of proxy voting by mutual fund and investment trust managers as a mechanism for increasing corporate value. FSA is currently encouraging the Investment Trust Association of Japan (ITAJ) to amend its rules on proxy voting to publicly disclose the summary results of its members' actual proxy voting records. ITAJ expects to decide the outline of the amendment to its rules in this regard this summer.

- c. The Government of Japan recognizes that it is desirable that private pension fund managers exercise proxy voting rights appropriately for the benefit of their beneficiaries. The Government of Japan will continue to study whether the adoption of a specific fiduciary duty regarding the exercise of proxy voting rights is appropriate, and will continue to monitor the trends and situations of proxy voting by pension funds.
2. Enhancing Corporate Governance and Facilitating Proxy Voting:
  - a. The Government of Japan recognizes the importance of enhancing corporate governance of listed companies and will engage in dialogues, as appropriate, with stock exchanges regarding their roles in realizing that goal.
  - b. As reference, the Tokyo Stock Exchange (TSE) adopted a rule, effective March 2006, that requires its listed companies to publish reports on the TSE website describing their corporate governance structure, including information on the reasons for adopting an in-house auditor or committee-style governance structure, whether they have outside directors and any measures against takeovers. The TSE amended its listing rules in 2006 to include, as a ground for delisting, the introduction of anti-takeover measures that seriously impinge on rights of shareholders, and now requires listed companies to promptly disclose details of any anti-takeover measures. Listed companies may consult with TSE as to whether measures to be introduced are consistent with the amended listing rules.
3. Court Review of Special Shareholder Resolutions: The Government of Japan confirmed that no statute of limitations is applicable to shareholder lawsuits challenging the legality of special shareholder resolutions on the grounds that the content of the resolution is in violation of the principle of equality of shareholder rights.

## **X. DISTRIBUTION**

### **A. Airport Landing and User Fees**

1. Airport fees are determined through discussion between the airport companies and the airlines. With regard to the Narita International Airport, the landing charges were reduced in 2005, and were accepted by the IATA.
2. The Government of Japan shares the view with the Government of the United States that airport user fees should be determined in accordance with ICAO Principles including transparency.
3. The Government of Japan noted that the Government of the United States

congratulated the Government of Japan on the re-opening of the impressive, modernized South Wing of Narita Terminal 1. The Government of Japan noted that the Government of the United States expressed the hope that the new facility would increase profit for NAA which may be reflected in moderation in airline user fees.

B. **Airline Sales Distribution:** The Government of Japan expressed its views on the concerns of the Government of the United States regarding Airline Sales Distribution.

C. **Airport Construction and Operation**

1. Narita International Airport Corporation (NAA), which was privatized in April 2004, has a strong incentive for profits. NAA's profit for the year ending March 2006 was 14 billion yen. NAA will carry out its B runway expansion in an effective and cost-conscious way.
2. This project will increase the capacity of the airport and enhance utilization by larger aircrafts with the B runway. For this reason, this project is supported by airlines and other countries, which have strong demands for more service to Narita, and will increase NAA's profit.

D. **Customs Prior Reporting Requirements**

1. In March 2006, the Customs Law was partly amended to require foreign trade vessels and aircraft to submit reports on information of cargo and passengers prior to arrival at open ports and Customs airports in Japan.
2. In drafting the bill, the comments submitted by relevant parties through public comment procedure in November 2005, and the report of the Council on Customs, Tariff, Foreign Exchange and Other Transactions in December 2005 were taken into consideration.

E. **Facilitation of Credit/Debit Card and ATM Services and Acceptance**

1. The Government of Japan recognizes the importance of maintaining the security level equivalent to internationally accepted security standards in ATM networks for banks in Japan. The Government of Japan also notes that hosts of banks' ATMs decide encryption standards for their networks, including complying with international PIN security and encryption standards.
2. The National Police Agency (NPA) is continuing to tighten regulations related to credit/debit card fraud in Japan. NPA is reinforcing cooperation with customs and immigration authorities and credit and debit card issuers and merchants to prevent smuggling and use of "raw" cards into Japan, which do not carry any personal information and could be used as materials for false cards, as well as illegal entry of criminal groups.

3. The Government of Japan took note of the request from the Government of the United States to promote the use of credit and debit cards as means of payment for government services. In addition, a study group established by the Ministry of Internal Affairs and Communications (MIC) is considering several aspects, including legal and technical, of introducing card payment for local government services. Based on these considerations, MIC submitted to the Diet the amendment of the Local Autonomy Law, which would enable the use of credit cards as means of payment for local government services. The amended Law was passed on May 31. The latest version of the Government's Three-year Plan of deregulation also calls for drawing a conclusion by the end of fiscal year 2006 whether to allow consumers to use credit cards to pay national taxes by examining various issues such as charges for cards. Also, some hospitals and parking lots operated by the Tokyo Metropolitan Government began accepting credit card payments in April 2005.

#### **F. Revision of the Road Transportation Vehicle Law**

1. After having discussed measures to lighten the burden on procedures of alternation registration and transfer registration for auto leasing companies and other owners of a large number of vehicles since June 2005, the experts compiled an interim report in December 2005.
2. The report recommended that vehicle registration procedures and the procedures for modifying vehicle inspection certificates be made independent by eliminating owner information from the vehicle inspection certificate in a case where the owner of a vehicle differs from the user. The report also proposed that from the standpoint of safe and smooth trade of vehicles, an online browsing system be established on vehicle registration information to ensure convenient and reliable procedures to check owner's information in vehicle distribution. In accordance with this report, the Ministry of Land, Infrastructure and Transport (MLIT) submitted the amendment of the Road Transportation Vehicle Law concerning the necessary revision to the Diet, which approved the bill on May 12, 2006. The bill will come into effect in 2008, but in order to ease the registration burden in the interim, MLIT has substituted a procedure whereby a new certificate of vehicle inspection is issued at the time of alternation or transfer of registration, and the original certificate of vehicle inspection can be returned to the relevant local transportation bureau after registration in a case where owners of a large number of vehicles apply for alternation or transfer of registration for their fleet whose users differ from the owner.
3. In December 2005, the Government of Japan started the partial operation of "One-Stop Service" for Motor Vehicle Registration that provides online application services for registering new vehicles in certain locations. "One-Stop Service" will be expanded to all procedures related to vehicle registration in all locations on an on-line basis by 2008.

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

1. With respect to the concern of the Government of the United States on the laws affecting large-scale retail stores, the Government of Japan has explained that it submitted bills amending the Central City Invigoration Law and the City Planning Law to the Diet on February 8, 2006. The Government of Japan has further explained that the purpose of the amendment of the Central City Invigoration Law is to overhaul and strengthen the current support measures on revitalizing the central urban areas.
2. The Government of Japan affirms that the purpose of the amendment of the City Planning Law is not to restrict the opening of large-scale retail stores but to ensure that large-scale facilities that attract a large number of people are located properly through the due procedures of city planning decisions. In areas where large-scale facilities would be restricted, those facilities may be located through due process of reviewing zoning amendment. In order to facilitate implementation of the procedure, the amended law will allow private developers to propose changes to a city's zoning plan.
3. The Government of Japan also affirms that the amended laws do not intend to restore the commercial adjustment system based on the consideration of economic demand and supply, and do not intend to restrict the business model of large-scale retail stores as such or the choice of consumers.
4. The Government of Japan affirms that the amended laws' implementing guidelines will be drafted in a transparent and fair manner that includes opportunities for the private sector as well as other interested parties to express views.
5. The Government of Japan notes the request of the Government of the United States that the Government of Japan review the impact of the City Planning Law in a timely manner after it comes into effect and in a manner that includes opportunities for the private sector as well as other interested parties to express views.

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

**I. CROSS-SECTORAL ISSUES CONCERNING REGULATORY REFORM AND COMPETITION POLICY**

**A. Trade/Investment Related Issues**

1. Anti-Dumping Measures and Safeguard Measures: The Government of the United States will ensure that its anti-dumping laws, regulations and other measures conform to its WTO obligations.
  - a. 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.
  - b. Section 801 of the U.S. Revenue Act of 1916 (Anti-dumping Act of 1916) was repealed on December 3, 2004.
  - c. With respect to the Hot-Rolled Steel WTO dispute, legislation was introduced in this Congress that would implement the Dispute Settlement Body's recommendations and rulings. 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.
  - d. The Government of the United States explained that the Steel Import Monitoring and Analysis (SIMA) System remains an automatic web-based import licensing system that is fully consistent with the WTO Agreement. The SIMA revision was open to public comment, and Japan's comments were fully considered.
  - 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.
2. The Federal Buy American Act and Other Related Rules: The Government of the United States takes note of the concern of the Government of Japan with regard to the Federal Buy American Act and Other Related Rules.

- a. The Department of Defense opposes legislative provisions that would undermine the longstanding U.S. policy to open U.S. procurement markets to suppliers from allied and friendly countries that open their procurement markets to U.S. suppliers.
  - b. The Government of the United States explained the implementing regulations under the Inter-modal Surface Transportation Efficiency Act of 1991 and takes note of the request by the Government of Japan for non-discriminatory treatment of goods with respect to implementation.
3. Re-Export Controls:
  - a. The Government of the United States acknowledges Japan's effective export control system by granting authorization without a license for certain re-exports from Japan that would normally require a license (i.e., under a License Exception). In response to the Government of Japan's concerns regarding United States re-export controls, the Department of Commerce has posted re-export guidance, translated into Japanese, on its website, <http://www.bis.doc.gov>, and has placed specifically trained personnel in Tokyo to assist with re-export control regulation inquiries.
  - b. The Government of the United States may consult with U.S. exporters on the issue of Export Control Classification Numbers to address the concern raised by the Government of Japan.
  - c. To address re-export control and other issues, the Government of the United States will have a continuing dialogue with members of Japan's Ministry of Economy Trade and Industry (METI).
4. Exon-Florio Amendment:
  - a. The Government of the United States recognizes the Government of Japan's concerns on the "Exon-Florio" amendment regarding, inter alia, predictability of regulations, legal stability of completed transactions, and ensuring due process. In implementing Exon-Florio, the Government of the United States is mindful of the Government of Japan's concerns.
  - b. The Government of the United States takes note of the concerns raised by the Government of Japan with regard to the recent debate in the United States on the CFIUS review process, and its concern that this could lead to hindering foreign investment in the United States. The Government of the United States is committed to an open economic system and will continue to welcome foreign investment, which contributes to economic growth.
5. Metric System:

- a. The National Institute of Standards and Technology (NIST) continues to promote the use of the metric system throughout the economy. Over 90 percent of U.S. states now permit the use of metric-only units on packages that are subject to their exclusive jurisdiction, including automotive accessories, clothing, and household furnishings. NIST is working with the remaining states to encourage those jurisdictions to amend their laws and regulations to permit voluntary metric-only labeling.
  - b. With respect to measures at the Federal Government level, NIST also continues to undertake efforts to develop industry and public support for an update to the Fair Packaging and Labeling Act (FPLA) that would permit metric-only labeling. A NIST working group, in late 2005, updated a report titled *Permissible Metric-Only Labeling*, aimed at raising awareness on this issue.
6. The Patent System of the United States: 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 and the first-to-file system is used in most countries although it remains controversial in the United States. Legislation to adopt the first-to-file approach is currently pending in the U.S. Congress (H.R. 2795 and proposed amendments thereto). In addition to this proposed legislation, the United States will also continue to pursue and participate in discussions with Japan and other WIPO Group B member countries on patent law harmonization, which includes discussion of draft provisions written from a first-to-file perspective.
  - b. *Early Publication System*: The United States is evaluating whether exceptions may be unwarranted in the early publication system. This issue is also addressed in the above-referenced legislation pending before the U.S. Congress, as well as in proposed legislation (H.R. 5096) introduced in the U.S. House of Representatives in April 2006.
  - c. *Reexamination System*: Changes to the U.S. reexamination system continue to be widely discussed, including new provisions to implement post-grant opposition proceedings, which are also addressed in proposed legislation (H.R. 2795 and H.R. 5096).
  - d. *Unity of Invention*: The Government of the United States recognizes that its standard of decision for unity of invention is more stringent than that of



the Patent Cooperation Treaty and is currently studying adoption of eased requirements for a unity of invention standard.

- e. *Hilmer Doctrine and Article 102(e) of the Patent Act*: The Government of the United States acknowledges that the Government of Japan has concerns regarding the Hilmer Doctrine and Article 102 (e) of the Patent Act. The Government of the United States notes that these issues are being discussed in the ongoing substantive patent law harmonization talks between the United States, Japan, and other WIPO Group B members. The United States will continue to pursue and participate in these discussions. These issues are also addressed in proposed legislation (H.R. 2795).
  - f. *Information Disclosure Requirement of Prior Art*: The Government of the United States recognizes Japan's concern with respect to the information disclosure requirement of Prior Art. As to Japan's concerns regarding translations, the Government of the United States notes that English translations are only required to be submitted if the translation is readily available. As to the Government of Japan's request to shorten the period of the information disclosure requirement, in the current view of the Government of the United States, applicants must timely disclose information that is known to be material to patentability at all times during patent prosecution and before the issuance of a patent. The Government of the United States notes the views of the Government of Japan and will evaluate the appropriateness of its measures with a view to ensuring that they do not impose undue burden on patent applicants.
  - g. *Plant Patent*: The Government of the United States notes the concern expressed by the Government of Japan regarding the difference in the novelty requirements in the patent laws and in Article 6 of the UPOV Convention. The Government of the United States would like to discuss with the Government of Japan what, in their view, are the important aspects of the novelty test according to the UPOV Convention, and how to address concern raised by the Government of Japan.
7. Harmonization and Unification of the State-based Licenses for Construction Business: 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. In order to facilitate further understanding of each state's practices, the U.S. Government has provided the Government of Japan with a comprehensive guide of state licensing information prepared by the National Association of State Contractors Licensing Agencies (NASCLA), a non-profit organization. The guide contains information on the various types of state licenses issued, laws, rules, policies, and reciprocal agreements. The U.S. Government noted the efforts of NASCLA to develop a national commercial contractor licensing examination by the end of this year. The U.S. Government

will provide the Government of Japan with relevant information on this issue, as appropriate.

8. Insurance Business Regulations:

- a. The National Association of Insurance Commissioners (NAIC) recognizes the benefits of harmonization of licensing and regulatory process. Efforts by the NAIC to harmonize state practices and streamline regulatory standards and processes for insurance products continue to advance under its 2003 Regulatory Modernization Action Plan. The following highlights are among the Plan's achievements to date:
  - (1) In addition to the adoption of standardized filing requirements and uniform standards for licensing among all U.S. states, the NAIC continues to implement its Financial Regulation Standards and Accreditation Program (the standards of which are in place in all U.S. jurisdictions) and to refine model laws in a number of areas, including with respect to annuities, reinsurance, long-term care, and health insurance.
  - (2) As of June 2006, 27 state legislatures have adopted the Interstate Insurance Product Regulation Compact, exceeding the threshold necessary for the Compact to take effect. An interstate commission will develop uniform national product standards and a central filing register to strengthen the speed and efficiency of regulatory decisions among member states in the areas of life insurance, annuities, disability, and long-term care insurance. The NAIC will continue to work with the states to encourage greater adoption of the Compact. Legislation to adopt the Compact is pending in the legislatures of an additional 10 U.S. states.
  - (3) A total of 52 insurance jurisdictions are utilizing the System for Electronic Rate and Form Filing, the electronic based system for enhancing speed and efficiency for insurance provider applications. As of the end of 2005, the system had logged approximately 185,000 electronic filings under this system.
- b. Following approval of a white paper in December 2005, the NAIC directed its Reinsurance Task Force in March 2006 to prepare proposals, by the end of 2006, for alternative treatment to provide reinsurance to unauthorized reinsurers. Task Force meetings and other related meetings are open to foreign interested parties, and input is solicited regularly from a group of interested parties, which includes representatives of Japan's insurance industry.

- c. The Government of the United States notes that the Government of Japan welcomes efforts to modernize the insurance regulatory system in the United States. The Government of the United States is aware that the Government of Japan has highlighted its interest in initiatives relating to federal-level oversight.
- d. The Government of the United States will continue to facilitate communications, as appropriate, between the Government of Japan and the NAIC on issues relating to state-based regulations. The NAIC has also provided a direct point of contact for issues raised by the Government of Japan, which will be directed within the NAIC to appropriate parties.

9. Protection of Credit Card Information:

- a. The Government of the United States recognizes the importance of protecting credit card information, and has enacted a combination of laws, regulations, and guidelines for this purpose. These measures, coupled with industry standards, strive to ensure the confidentiality of sensitive customer data and credit card information by both banks and credit card processing companies. A group of Federal Departments and Agencies share responsibility for enforcing federal information security laws and associated regulations and guidelines.
- b. U.S. Government regulators supervise and examine banks and other financial institutions for their compliance with, among other things, data security laws and regulations. These regulations require a financial institution to contractually oblige its third party data processors to implement appropriate data security measures. Financial institutions also must, when appropriate, monitor the third party's implementation of such measures. In some cases, a U.S. Government examination may include directly examining the data security practices of a financial institution's third party data processor. In addition, U.S. Government regulators have issued guidance, and industry groups have developed standards to assist financial institutions in protecting consumer information and complying with applicable laws and regulations.
- c. The FTC Act and the Gramm-Leach-Bliley Act are two examples of legislation used to bring enforcement actions against companies found to have inappropriate safeguards to protect sensitive customer information, or that engage in unfair or deceptive acts or practices in collecting or handling consumer information. The FTC has prosecuted thirteen data security cases based on these Acts, including a case against a third party processor.
- d. The Government of the United States will continue its efforts to prevent recurrence of unauthorized disclosures of credit card information.

- e. The Governments of the United States and Japan will continue to exchange information on these issues. To facilitate discussion between experts, the Government of the United States prepared a contact list of U.S. Government experts who are prepared to discuss issues of credit card protection with the Government of Japan.

**B. Consular Affairs**

1. Visa Process:

- a. *Efficiency in Visa Revalidation Procedures:* The Government of the United States is interested in exploring ways to facilitate visa processing, using technology where possible to improve security while making it easier for legitimate travelers to obtain visas and renew them, as noted in the Rice-Chertoff Initiative announced in January 2006.
  - (1) The Government of the United States understands the serious concerns raised by the Government of Japan about the difficulties the Japanese business community in the United States is facing with regard to domestic visa re-validation and will continue to evaluate the feasibility of re-opening revalidation within the United States.
  - (2) The Department of State is exploring ways to streamline E visa applications and make it possible for more posts to accept renewal applications from third country nationals. The Government of the United States and the Government of Japan will continue to engage in regular dialogue on visa issues.
- b. *Introduction of Visa Services into the Other Consulates in Japan:* The Government of the United States responded to the request by the Government of Japan to expand visa services in Japan by starting monthly non-immigrant visa processing on a pilot basis in the United States Consulate in Sapporo from April 19, 2006. If successful and cost effective, the Government of the United States will continue this program and consider expanding within Japan and in other parts of the world.
- c. *Visa Issuance and Terms of Validity:*
  - (1) The Government of the United States notes the concern raised by the Government of Japan from the reciprocal point of view that L visas are valid only for two or three years while intra-company transferees to Japan are provided with five-year visas.

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

2. Driver's License:

- a. The Department of Homeland Security (DHS) is in the process of developing regulations that will establish the minimum standards for State governments to follow when issuing driver's licenses or other forms of State-issued identification, pursuant to the Real ID Act, signed into law by President Bush on May 11, 2005, and scheduled to take effect in 2008.
- b. All States have entered into a Memorandum of Understanding (MOU) with DHS to verify the legal presence of all non-citizen drivers' license applicants using the Systematic Alien Verification for Entitlements (SAVE) to verify a driver's license applicant's lawful status. For all non-citizens authorized to be in the United States for a temporary period, the Real ID Act states that the validity period of a driver's license or identification card issued by the State may not exceed the period of authorized stay.
- c. How States will implement the new law's provisions remains unclear at this point. The Act accords the Secretary of Homeland Security, in consultation with the Secretary of Transportation and the States, the authority to issue regulations, certify compliance, and issue grants pursuant to the Act. DHS expects to publish a Notice of Proposed Rule-Making in the Federal Register this calendar year. The proposed rule will be open for public comment. The Government of the United States understands the concerns raised by the Government of Japan. DHS will continue to seek input from stakeholders as regulations are developed, and acknowledges the request of the Government of Japan that, in the course of the implementation of the Act, States should also consider the issues currently affecting Japanese and other foreign nationals as a result of States' driver's license regulations. DHS welcomes the participation of the Government of Japan in the public comment period of the rule-making process.
- d. The Government of the United States recognizes that the Government of Japan is concerned about some State regulations regarding driver's license, including international driver's permits, State of Michigan identification requirements, State of Massachusetts sponsor requirements, States of Tennessee and Utah driver's certificates, and State of Rhode Island driving test location requirements.

3. Immigration Control by Use of Biometric Identifiers:

- a. US-VISIT – a top priority of the U.S. Department of Homeland Security – enhances security for U.S. citizens and visitors while facilitating legitimate travel and trade across U.S. borders.
- b. DHS deployed US-VISIT biometric entry capabilities to 115 airports, 15 seaports and in the secondary inspection areas of 154 land border ports of entry before the congressionally mandated deadlines of December 31, 2004 and 2005. US-VISIT biometric exit procedures are in place at 12 U.S. airports and 2 seaports throughout the country.
- c. As US-VISIT moves toward fulfilling its vision for an automated entry-exit system at the land border ports of entry into the United States, US-VISIT is continuing to improve border management testing radio frequency identification (RFID) technology at 5 U.S. land border ports of entry. As of May 2006, over 56 million foreign visitors have been enrolled in US-VISIT, with no significant increase in wait times. More than 1,100 individuals with criminal backgrounds or histories of immigration violations have been denied entry by U.S. Customs and Border Protection Officers based on the biometric information provided by US-VISIT.
- d. US-VISIT meets regularly with the Government of Japan through its Embassy in Washington, D.C. These discussions address public education, privacy, and operational issues. US-VISIT has an extensive outreach program to inform the Government of Japan, the travel industry and the public about the US-VISIT requirements of the US-VISIT program and what to expect when entering or exiting the United States.
- e. Information on the US-VISIT program is available in Japanese on the Embassy Tokyo website. The U.S. Government continues to welcome suggestions by the Government of Japan for further dissemination of this information.
- f. The Government of the United States fully understands and shares the Government of Japan's concerns about protecting its citizens' personal information. That information will be stored in databases maintained by DHS and the State Department as part of an individual's travel record. The system will be available to U.S. Customs and Border Protection Officers at ports of entry, special agents in U.S. Immigration and Customs Enforcement, adjudications staff at U.S. Citizens Immigration Services offices, and United States consular offices - and appropriate federal, state, and local law enforcement personnel on a need to know basis. The program will be implemented in compliance with US-VISIT established privacy policies and the privacy impact assessment. US-VISIT is staffed by a privacy officer who specializes in this program and works in close cooperation with other DHS privacy officers to ensure adherence to

government-wide privacy principles. The DHS privacy officer reviews pertinent aspects of the US-VISIT program to ensure that proper safeguards are in place. The United States protects the biometric identifiers of foreign nationals collected by US-VISIT under the same level of privacy standards as they would to United States citizens' personal information. Safeguards have also been implemented to ensure that the data is not used or accessed improperly.

4. Suspension of Visa Waiver Program for Holders of Non-Machine-Readable Passports:

- a. The Assistant Commissioner of Field Operations for U.S. Customs and Border Protection (CBP) sent a letter September 12, 2005, to the Japanese Embassy in the United States indicating the conditions under which CBP would grant a parole to nationals of Visa Waiver Program (VWP) countries with non-machine-readable emergency or temporary passports. Such VWP travelers must meet the following conditions: 1) must have had a passport lost, stolen or expired while outside the home country; 2) must present an emergency or temporary passport or other emergency travel document issued by a government authority to replace a lost or stolen passport; 3) must be in direct and continuous transit through the United States for the purpose of returning home; 4) must have confirmed airline tickets (or electronic ticket record) for return to the home country; 5) must be otherwise admissible to the United States; and 6) will be required to pay the \$65 parole fee if granted a parole.
- b. Other than the above, all passports used for VWP travel must be machine-readable. In addition, regular passports issued on or after 10/26/05 must contain a digital photo; regular passports issued on or after 10/26/06 must contain an integrated circuit chip. Official, diplomatic, emergency, and temporary passports, however, are only required to be machine-readable for VWP travel. Except as noted above, travelers whose passports do not meet the machine-readable and, as appropriate, digital photo and chip specifications are required to obtain visas to visit the United States. The Government of the United States is reviewing how travelers with the Return to Japan Travel Document would be handled per VWP documentary requirements and procedures. Outreach efforts have been made to inform VWP countries of the October 26, 2005, digital photo requirement; such efforts have helped reduce the number of VWP visitors arriving in the United States without proper passport. The Governments of the United States and Japan will exert further efforts to make sure that the public, travel industry and airlines are informed of the VWP passport requirements, including the requirement that the passports issued on or after October 26, 2006, must include an integrated circuit chip.

5. Social Security Number (SSN):

- a. *Shorter Period for SSN Assignment Process:* The Social Security Administration (SSA) must verify the immigration status of all non-citizens before assigning an SSN or issuing a Social Security card. Within the last year, the SSA and the Department of Homeland Security (DHS) have continued efforts to improve timeliness in verifying immigration status. They are currently working to implement a WEB based verification system, which will further reduce delays in verification and result in fewer SSA referrals to DHS for manual (paper) verification of documents. The Government of the United States will continue these efforts, taking into consideration the request by the Government of Japan in this regard. The Government of the United States is currently studying the feasibility of expanding the Enumeration at Entry Program to other categories of non-citizens.
  - b. *Issuance of Social Security Numbers to the Dependents of Employment Visa Holders:* The Government of the United States fully understands the concerns of the Government of Japan regarding the assignment of SSNs for dependents of employment visa holders. The Government of the United States recognizes an individual as eligible for an SSN if they have DHS work authorization or if they have a valid non-work reason for an SSN.
6. Individual Taxpayer Identification Number: The Internal Revenue Service (IRS) notes the concern raised by the Government of Japan with regard to Individual Taxpayer Identification Number (ITIN), and appreciates that an undue delay in the issuance of an ITIN can create an inconvenience, and will consider how to improve customer service in this regard.
7. Permission to Stay (I-94): The Government of the United States notes the request by the Government of Japan that the term of validity of Permission to Stay (I-94) be extended.
- a. U.S. Citizenship and Immigration Services (USCIS) has prioritized backlog elimination in its FY2006 budget, submitted in February 2005, requesting an overall 4 percent increase over the FY2005 budget, and earmarking a total of \$100 million specifically for backlog elimination efforts. To date, USCIS has made significant strides towards accomplishing its backlog elimination goals.
  - b. USCIS has set the agency's priorities as (1) ensuring national security, (2) reducing the backlog, and (3) improving customer service. Since it was established in 2003, USCIS has, among other things, expanded electronic filing of applications and benefits to support 50 percent of the total volume; and expanded the ability



for customers to access case status information via the USCIS website. USCIS will continue these efforts.

## C. **Distribution**

1. Maritime Transport Security: The Government of the United States shares with the Government of Japan an understanding of the importance of balancing security considerations with the need to facilitate international trade. The security and efficiency of the international supply chain and the maritime transportation system that supports it are critical to global prosperity. From this point of view, the Government of the United States notes Japan's request regarding this issue and is committed to balancing its initiatives for counter-terrorism with rapid, smooth and effective distribution. The Government of the United States is also committed to working with the international community to develop common procedures and standards that will complement modern business practices while improving public safety. The International Ship and Port Facility (ISPS) Code which has set a common standard for assessing ship and port facility security is an example of the success that can be achieved through international partnership. The Government of the United States continues to work with the World Customs Organization (WCO) to implement the *Framework of Standards to Secure and Facilitate Global Trade* which will secure trade in such a way that facilitates the secure movement of commerce and economic prosperity. We appreciate the efforts of Japan to support capacity building to implement the *Framework*, and the support we have received for the Container Security Initiative (CSI). The Department of Homeland Security Secretary Michael Chertoff's March 2006 visit to Japan confirmed the commitment of the United States to deepening cooperation the Government of Japan on a wide range of issues.
  - a. *Advance Electronic Presentation of Cargo Information*: Advance information and strategic intelligence allow the identification of cargo shipments that pose a potential risk to safety and security before the cargo is loaded on vessels. This risk management approach to cargo processing is becoming a recognized international best practice. The advancement of modern business information systems increasingly creates opportunities for risk analysis earlier in the supply chain, providing multiple opportunities to resolve potential threats. The Government of the United States worked closely with the trade community in developing the regulations to implement the advance electronic information requirements of the Trade Act. The requirements were gradually implemented recognizing the adjustment necessary in business processes. These requirements mandate a reasonable timeframe to allow the analysis of the information so that only safe cargo will enter the maritime transportation system. The Government of the United States notes Japan's concern that, as the private sector adapts to the new requirements, this approach can affect efforts by importers to shorten lead times within their supply chains. The Government of the United States welcomes the internal efforts of the

Government of Japan's Promotion Council to shorten the lead time of exports to the United States. Taking note of the request of the Government of Japan with regard to deregulation of the advance presentation of electric cargo information, the Government of the United States will continue to work to enhance the compatibility between thorough security measures and efficient distribution, and continue working with the international community through organizations such as the International Maritime Organization and the World Customs Organization to achieve greater international uniformity in requirements for the international transportation of cargo.

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

2. The Bioterrorism Act and Related Regulations:

- a. 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 now is carefully considering all comments it received during an open comment period on the 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.

- b. 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>
- c. The United States Embassy in Tokyo recognizes and appreciates the high level of interest in compliance with the Bioterrorism Act by Japanese food processors, Japan Post, commercial express delivery service providers, and the general public in Japan. The Embassy will endeavor to provide relevant information on its website in Japanese regarding any significant developments under the Bioterrorism Act that may give impact on food processors and senders in Japan. The Government of the United States will also, in close consultation with the Government of Japan, develop user-friendly materials that are easily available through its Embassies and Consulates to assist Japanese and other foreign nationals, individual food senders and small and medium-sized food processors in particular, in complying with the Bioterrorism Act. The Embassy welcomes further discussion with the Government of Japan and interested parties on how to efficiently and effectively improve outreach regarding the Act.

3. Interstate Weight Limits:

- a. The Government of the United States notes the concerns of the Government of Japan that the Interstate weight limits set by the federal law could affect transport costs. The Department of State has consulted with the Office of Freight Management and Operations (FMO) of the Department of Transportation's Federal Highway Administration (FHWA) regarding the recommendations of the Government of Japan concerning Interstate weight limits.
- b. States have the option to consider, as "non-divisible loads," cargoes that are carried in containers moving in international commerce (i.e., either originating in another country or destined thereto). Various, but not all, States have chosen to exercise this option. Thus, if State policy allows containers moving in international commerce to be issued permits as non-divisible loads, a State can issue an overweight permit allowing the loads on the Interstate. As each State is responsible for operating and maintaining their highway transportation infrastructure and has the most complete knowledge of what routes within that infrastructure can support

or accommodate overweight movements, they are currently and should continue to be the permitting authority for overweight movements. The FHWA has consolidated on its own website the various State websites and contact information for obtaining overweight permits.

- c. The Government of the United States and the Government of Japan will continue to exchange views and information on this issue. FHWA/FMO's Commercial Vehicle Size and Weight Team has offered to brief the Government of Japan on the federal weight limits, and to discuss any additional concerns.

4. Maritime Transport Legislation:

- a. *Merchant Marine Act of 1920 and the Reporting Requirement on the Situation of Japanese Ports:* The Government of the United States and the Government of Japan exchanged views regarding the Merchant Marine Act of 1920. The executive agencies of the United States will continue to consult and exchange information with the Government of Japan and will keep the Federal Maritime Commission (FMC) informed of the situation of Japanese ports.
- b. *Ocean Shipping Reform Act of 1998:* The Government of the United States and the Government of Japan exchanged views on the Ocean Shipping Reform Act of 1998. The Government of the United States took note of the concern of the Government of Japan.

5. Abolition of Maritime Security Program: The Government of the United States exchanged views with the Government of Japan and will continue to ensure that the Government of Japan is kept informed of the list of the dedicated vessels and any changes in this important national security measure.

6. Cargo Preference Measures: The Government of the United States and the Government of Japan exchanged views on Cargo Preference Measures, including the law requiring that the transport of Alaskan North Slope crude oil be done on U.S.-flag ships. The Government of the United States took note of the opinion of the Government of Japan that measures such as cargo preferences may distort conditions for free and fair competition in the international maritime market. With respect to these issues, the Government of the United States explained the following:

- a. United States Government-owned cargoes covered by cargo preference laws, including the transport of U.S. military cargo, represent less than one percent of the United States' total ocean borne foreign trades; and

- b. 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.

7. Regulation Regarding Alcohol:

- a. *On-sale License in State of California:* The Government of the United States notes the concerns of the Government of Japan regarding the sale of shochu in the State of California and will convey the Japanese request to the State of California. In addition, the Government of the United States notes that the Government of Japan is free to petition the State of California for an exemption from State regulation, or request that the relevant State law or regulation be amended to allow for the sale of shochu for consumption on the premises where sold.
- b. *Certificate of Label Approval on Alcoholic Beverages:* The Government of the United States notes the views of the Government of Japan regarding the labeling of alcoholic beverages, and notes that Federal law requires such labeling (Federal Alcohol Administration (FAA) Act at 27 U.S.C. § 205(e)). The Government of the United States also notes that the regulations of the Alcohol and Tobacco Tax and Trade Bureau of the Treasury Department (TTB) (27 C.F.R. § 27.74) exempt some commercial samples used to solicit orders from foreign countries from these Federal requirements, as well as some display samples used for trade fairs approved by the U.S. Department of Commerce pursuant to the Trade Fair Act of 1959. In order to take advantage of this limited exemption from the Certificate of Label Approval (COLA) used for soliciting orders, the importer must meet the requirements of 27 C.F.R. § 27.49 which are as follows:
  - (1) The exemption applies to one sample of each alcohol beverage admitted during a calendar quarter for each person. That is, each importer may bring in one sample of an alcohol beverage without a COLA.
  - (2) No sample of beer shall contain more than 8 ounces, for wine no more than 4 ounces, and for distilled spirits no more than 2 ounces.
  - (3) The health warning statement must be affixed to the sample. See 27 U.S.C. § 215(a).
  - (4) It is possible to obtain an exemption from COLA requirements and Federal excise taxes for larger amounts of alcohol beverages used in trade fairs “designated” by the U.S. Department of Commerce pursuant to the Trade Fair Act of 1959. The exemption only applies to alcohol beverage products used for “display purposes” at

the trade fair and such products must be labeled accordingly. Once the fair is “designated”, the importer must apply to TTB for COLA exemption. Importers may contact TTB at the following address: Director, International Trade Division, Suite 400W; Alcohol and Tobacco Tax and Trade Bureau; 1310 G St., NW; Washington, D.C. 20220.

## D. Sanctions Acts

### 1. Iran and Libya Sanctions Act:

- a. The Government of the United States appreciates having the views of all its trading partners on this matter, including those of the Government of Japan. In response to the issues raised by the Government of Japan, the Government of the United States explained that by its terms, the Iran and Libya Sanctions Act (ILSA) applies to those who engage in activities covered by the statute, without distinction by nationality. It was explained that 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 will continue to have a dialogue with the Government of Japan on these issues. The Government of the United States notes that legislation has been introduced in Congress that would amend ILSA in significant ways.
- b. The United States again notes that the scope of ILSA was significantly changed in April 2004, when its application to Libya was terminated in response to Libya’s progress in dismantling its weapons of mass destruction and longer-range missiles.

### 2. Cuban Liberty and Solidarity Act of 1996:

- a. The Government of the United States understands the concerns of the Government of Japan regarding the Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 (Public Law 104-114). Since the enactment of the Act, the President has, every six months, suspended the right to bring an action under Title III (which provides for civil suits against persons who traffic in expropriated property), based on findings that such suspension is necessary to the national interests of the United States and will expedite a transition to democracy in Cuba. The duration of the suspension is fixed by statute and cannot exceed six months at a time. P.L. 104-114, Sec. 306.
- b. Most recently, on January 17, 2006, the President sent a letter to Congress consistent with the Act to suspend for six months beyond February 1, 2006, the right to bring an action under Title III of the Act.

3. Sanctions Acts Instituted by Local Governments: The Government of the United States has made considerable efforts over the years to reach out to state and local authorities to help ensure that initiatives at the state or local level support U.S. foreign policy. The Government of the United States will continue those efforts when needed, mindful of any relevant international obligations.

## E. **Competition Policy**

### 1. Antitrust Exemptions:

- a. The federal antitrust agencies of the United States continue to look for opportunities to express their views on the appropriate scope and reach of limitations on and exemptions to the application of the federal antitrust laws from the standpoint of promoting competition for the benefit of consumers in the United States. In this regard, in January 2006 the United States filed a brief with the U.S. Supreme Court in *Gosselin World Wide Moving N.V. v. U.S.*, urging the Court to decline to review a decision by the U.S. Court of Appeals for the Fourth Circuit that there was no antitrust immunity provided by the Shipping Act of 1984 for an agreement to rig the bids on the through rates submitted by U.S. freight forwarders to the Department of Defense to transport military and civilian household goods to the United States.
- b. The United States Department of Justice (DOJ) and the Federal Trade Commission (FTC) have been actively submitting comments to state governments and related entities encouraging them to minimize or eliminate impediments to competition. For example, on October 18, 2005, DOJ and FTC submitted joint comments to the Michigan Senate and Michigan Department of Labor & Economic Growth urging the Michigan legislature not to adopt legislation that would require all real estate brokers to provide a minimum package of real estate services, thereby preventing consumers from saving money by purchasing only the services that they want. In November 2005, DOJ wrote a similar letter to the New Mexico Real Estate Commission urging it not to adopt proposed regulations that would have had the same effects as the Michigan bill.
- c. In September 2005, staff of the FTC testified before the Antitrust Modernization Commission, a body charged by statute to examine whether the federal antitrust laws require modernization and to issue recommendations for specific changes. In the testimony, FTC staff recommended that the state action doctrine be clarified to, among other things, reaffirm the requirement for immunity from the federal antitrust laws that the intent to displace competition be clearly articulated by the state sovereign and strengthen the requirement that the state sovereign actively supervise the conduct that supplants competition.

- d. Postal reform legislation that contains provisions designed to subject certain activities of the U.S. Postal Service to the antitrust laws has passed both houses of Congress. The legislation has been referred to Conference Committee for deliberation.
2. Release of Documents and Materials on Antitrust Enforcement Activities:
- a. FTC, in January 2006, revised its Internet homepage to provide access to three different competition enforcement activities reports that are prepared annually. Two of those reports include annual statistics and brief summaries of merger and nonmerger enforcement actions taken by the FTC, including consent orders, administrative complaints and decisions, and federal court decisions. The third report – the annual report to the U.S. Congress pursuant to the Hart-Scott-Rodino Antitrust Improvements Act (“HSR Act”) jointly prepared by FTC and DOJ -- provides a summary of merger enforcement-related activities by both agencies, including statistics on administrative and federal court complaints and decisions, and consent orders.
  - b. DOJ issues press releases announcing the filing of all of its antitrust criminal prosecutions and civil enforcement actions. The vast majority of the press releases related to criminal prosecutions involve the filing of a criminal. Information that is accompanied by a plea agreement which includes a summary of the violation and the recommended sentence. Similarly, the vast majority of DOJ’s civil enforcement actions are settled by consent decree, which DOJ publishes on its website along with a Competitive Impact Statement that includes a summary of the violation and the terms of the proposed remedy. The Final Judgment entered by the Court is also published on the DOJ website.
  - c. The Department of Justice will provide the Japan Fair Trade Commission, upon request, with information concerning the results of particular antitrust criminal prosecutions and civil enforcement actions.

**F. Legal Services and Other Legal Affairs**

1. Acceptance of Foreign Lawyers as Foreign Legal Consultants:
- a. 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.
  - b. The ABA GATS Task Force plans to issue a report this summer recommending that the ABA liberalize its Model Rule at the ABA’s Annual Meeting in August 2006. The suggested liberalizations will



include shortening the recommended period of prior legal experience and lowering (or even eliminating) the minimum age for foreign lawyers seeking to be licensed as a foreign legal consultant.

- c. At the Annual Meeting, to be held this year in Honolulu, Hawaii, the ABA GATS Task Force will be hosting on August 5 a "summit" of bar leaders from states of the greatest interest to foreign lawyers and from bar regulatory entities and bar associations from countries in the Pacific region. Prior "summits" with European bar leaders proved to be useful opportunities for frank exchanges of views among the participants that focused on reciprocal opportunities for access to the markets for legal services of all involved.
- d. In December 2005, the state of Texas liberalized its Foreign Legal Consultant Rules. Among the changes to those Rules, foreign lawyers now must only have practiced the law of their home country in three of the previous five years to be certified as a foreign legal consultant, and that legal experience may be acquired in any jurisdiction, including in third countries.
- e. The Government of the United States will continue to consider the recommendations of the Government of Japan regarding foreign legal consultant systems in the United States and will inform the Government of Japan of any results.

2. Product Liability Law:

- a. The Government of the United States is strongly committed to alleviating the undue burden on the business community from inappropriate product liability litigation and unreasonable awards for damages, and has supported a number of bills to that end.
- b. In January 2006 the Food and Drug Administration (FDA) issued a final rule on Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products. That rule introduces new requirements regarding the format of drug labeling and regarding the emphasis placed on safety information (such as warnings). The rule further states that product liability lawsuits in state courts based on claims that the content or formatting of prescription drug labeling is not consistent with state law requirements will be preempted in various circumstances, including where state law (i) would require safety information different from or in addition to safety information on the FDA-approved label or under consideration by FDA, or (ii) would require a different emphasis on warnings or contraindications than that set forth in the FDA-approved label.

- c. In March 2006 the Consumer Products Safety Commission (CPSC) promulgated a final rule on the Standard for the Flammability (Open Flame) of Mattress Sets. In the preamble to that rule, the CPSC states that it expects that the new mattress flammability standard “will preempt inconsistent state standards and requirements, whether in the form of positive enactments or court created requirements.” The CPSC rule should effectively preclude product liability lawsuits under state law based on claims that the manufacturer was liable for failing to comply with any standard or other regulation that addresses the same risk of occurrence of fire which is not identical to the federal requirement.
  - d. The Government of the United States strongly supports enactment of medical liability reform and asbestos litigation reform legislation to expedite resolution, and curb the cost, of lawsuits. To that end, the Administration will continue to work with the Congress to pass meaningful reform legislation.
3. Punitive Damages: The Government of the United States takes note of the concerns of the Government of Japan regarding punitive damages, and will continue to discuss this issue with the Government of Japan.

## II. TELECOMMUNICATIONS

- A. **Participation in the U.S. Wireless Market**: The Government of the United States will continue to provide information to the Government of Japan on the classification between common carriers and non-common-carriers and the distinction between tariffed and non-tariffed services in the United States.
- B. **Certification and Licensing Criteria Deregulation and Reporting Requirements for Foreign Operators**
  1. In discussing licensing criteria for foreign carrier entry into the U.S. telecommunications market, the Government of the United States explained that telecommunications licensing conditions are administered with a view to avoiding any unreasonable restrictions on foreign participation in the United States market.
  2. The Telecommunications Act of 1996 requires the Federal Communications Commission (FCC) to review the rules issued under the Telecommunications Act that apply to telecommunications service providers to determine whether any regulations are no longer necessary in the public interest due to meaningful economic competition and whether such regulations should be repealed or modified. The Government of the United States welcomes the Government of Japan’s participation in biennial reviews and will seriously consider any recommendation on its merits.
- C. **State-Level Regulations**

1. The Government of the United States continues to provide the Government of Japan relevant information on any NARUC work to harmonize state-level regulations.
2. The Government of the United States will continue a dialogue with the Government of Japan regarding state-level regulations, including licensing procedures, the Government of Japan's interest in regulatory harmonization among states, and adoption of unified reporting requirements.

**D. Regulatory Reform in the Broadband Era**

1. Dichotomous Classification of Telecommunications Service and Information Service: The Government of the United States will continue to provide information to the Government of Japan on relevant developments relating to any possible review of the regulatory dichotomy between Information Service and Telecommunications Service.
2. IP-Enabled Services: The Government of the United States will continue a dialogue with the Government of Japan on how the FCC implements its June 2005 decision to require that certain providers of voice over Internet protocol (VoIP) phone service supply enhanced 911 (E911) emergency calling capabilities to their customers as a mandatory feature of the service.

**E. Universal Service:** The Governments of the United States and Japan reaffirmed their continued intention to maintain any universal service mechanism consistent with WTO Reference Paper commitments.

**F. Access Charges:** The Government of the United States recognizes the complexity inherent in maintaining different kinds of access charges: reciprocal compensation, intra-state access charge and inter-state access charges, and is working towards a unified intercarrier compensation regime, with a view to rationalizing multiple charging mechanisms.

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

1. The Government of the United States will continue its efforts to minimize delays and maximize transparency of procedures in export licensing and Technical Assistance Agreements (TAA) approval for commercial communications satellites in accordance with U.S. laws, regulations, and policies.
2. The Governments of the United States and Japan have conducted an earnest dialogue on export licensing for commercial satellites. Recognizing the importance of U.S.-Japan relations, the Governments of the United States and Japan will continue this dialogue on this issue.

- H. **Competition in the Navigation Devices Market in the Process of Transition to Digital Television:** The Government of the United States will continue a dialogue with the Government of Japan on how the FCC enforces Section 629 of the Telecommunications Act with a view to ensuring choice in the market for navigation devices (set top boxes).
- I. **Consumer Access to Internet Applications, Content, Devices and Services:** In September 2005, the FCC adopted a policy statement intended to ensure that broadband networks are widely deployed, open, affordable, and accessible to all consumers.
- J. **Promotion of New Telecommunications Technologies**
1. The Telecommunications Working Group of the Regulatory Reform Initiative held a meeting of government officials and private sector experts and exchanged opinions on resolving interference issues in commercial deployment of high-speed Power Line Communications (PLC) in Japan and Broadband Over Powerline (BPL) in the United States. In October 2004, the Government of the United States introduced rules that have facilitated the commercial deployment of BPL.
  2. By the end of 2006, the FCC intends to auction 90 Megahertz of spectrum for advanced wireless services (in the 1710-1755 MHz and 2110-2155 MHz bands), which will be made available to commercial mobile radio service operators on a technologically-neutral basis.
- K. **Promotion of Trade in Telecommunications Equipment**
1. The Governments of the United States and Japan will continue formal negotiations with a view to an early conclusion of a Mutual Recognition Agreement (MRA) relating to conformity assessment of telecommunications equipment.
  2. Regarding electromagnetic compatibility (EMC), the Governments of the United States and Japan will continue to work together to develop an arrangement that would permit acceptance of results of conformity assessment for information technology (IT) equipment and industrial, scientific and medical (ISM) equipment conducted by accredited Japanese conformity assessment bodies.
- L. **Network Channel Terminating Equipment (NCTE):** Procedures established in the 1990 Letters on Network Channel Terminating Equipment (NCTE), and revised as per the Third Report to the Leaders, ceased to be applied in and after FY2006, after a public comment procedure. Under Article 23 of the Telecommunications Business Law, carriers providing designated telecommunications services are obligated to disclose the technical requirements of NCTE.

### **III. INFORMATION TECHNOLOGY**

#### **A. Cooperation in Efforts against Counterfeits and Pirated Goods**

1. To combat the serious and growing problem of piracy and counterfeiting, both the Governments of the United States and Japan have implemented new initiatives under their respective domestic IPR programs -- the Strategy Targeting Organized Piracy (STOP) in the United States and the “Intellectual Property Strategic Program 2005” in Japan. Notable new initiatives realized in 2006 include:
  - a. Strategy Targeting Organized Piracy: Passage of the “Stop Counterfeiting in Manufactured Goods Act”, establishment of a Global IPR Academy, and expansion of IPR experts abroad.
  - b. Intellectual Property Strategic Program 2006: Aiming for an early realization of an international legal framework on preventing proliferation of counterfeits and pirated goods, strengthening the regulations of private import, etc.; and preventing the sale of counterfeits and pirated goods via internet auctions.
2. In addition to establishing their own initiatives in this area, the Governments of Japan and the United States have been and will continue to closely cooperate on strengthening IPR protection and enforcement. Along with cooperating multilaterally, the two Governments, for example:
  - a. Held bilateral meetings regularly to promote IPR protection and enforcement in Asia Pacific and around the world, and
  - b. Co-sponsored under the APEC Anti-Counterfeiting and Piracy Initiative, model guidelines to reduce trade in counterfeit and pirated goods, to prevent against unauthorized copies, and to prevent the sale of counterfeit and pirated goods over the Internet, which was endorsed at the meeting of APEC Leaders and Ministers for Trade in November 2005 in the Republic of Korea.
3. The Governments of Japan and the United States will continue to cooperate in bilateral, regional, and multilateral fora to promote greater protection for IPR world wide by undertaking further actions on a wide range of initiatives, such as the APEC Anti-Counterfeiting and Piracy Initiative and WTO TRIPS transparency request, among others. The Governments of Japan and the United States will expand cooperation to address IPR problems in China using appropriate tools. In addition, the Governments of Japan and the United States will continue to discuss the idea introduced by Prime Minister Koizumi at the G8 Gleneagles Summit in July 2005 regarding a possible international agreement to address the proliferation of counterfeit and pirated goods.

4. The Governments of Japan and the United States have discussed under the Regulatory Reform Initiative ways to cooperate to combat piracy of digital content.
5. The Governments of Japan and the United States will continue to seek and explore possibilities to cooperate with companies and industry associations to arrange joint conferences or seminars to discuss IPR protection strategies. This would include sharing information on IPR enforcement activities.

**B. Protection of Copyright and Related Rights**

1. Protection for and enforcement of copyrighted works in the digital age is important to the Governments of the United States and the Government of Japan.
2. The Government of the United States recognizes the importance of ensuring the protection of the rights concerning live performances and moral rights. The Government of the United States recognizes the importance the Government of Japan places on the protection of the rights concerning unfixed works.
  - a. Protection of these rights is provided in the United States through a combination of rights under the Copyright Act, state common law, and other Federal and state laws. The Government of the United States will continue to take adequate measures to ensure transparency regarding the protection of these rights.
  - b. The Government of the United States recognizes that protection of rights concerning the fixation, broadcasting by wireless means and the communication to the public of live performances are required under TRIPS article 14 and WPPT article 6. The Government of the United States recognizes that the Government of Japan considers this right to include rights concerning non-musical performances.
3. The Government of the United States recognizes the importance of the right of making available, as required by the WIPO Internet treaties, as well as the importance the Government of Japan places on this right. The Government of the United States recognizes that the smooth 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.
4. 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.

C. **Adequate Protection of Rights under the Digital Millennium Copyright Act (DMCA):** The Governments of the United States and Japan recognize the importance of striking an appropriate balance between the copyright owner's rights and the alleged infringer's rights of privacy and freedom of expression relating to online infringement and the use of subpoena's pursuant to section 512(h) of the U.S. Copyright Act to obtain identifying information about a subscriber suspected of copyright infringement. In this connection, the Governments of the United States and Japan will observe future developments, and continue to discuss issues in this area.

D. **Response to Digital Networking**

1. The Government of the United States will continue to exchange information with the Government of Japan on "access controls" under section 1201 of the U.S. Copyright Act, which was added by the Digital Millennium Copyright Act (DMCA).
2. The Government of the United States will take appropriate measures to ensure that the protection of "access controls" will not adversely affect non-infringing uses of copyright protected works, such as fair use of copyrighted works, so that their protection will be supported by all relevant stakeholders.
3. The Government of the United States recognizes that WCT Article 11 and WPPT Article 18 requires adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used in connection with the exercise of copyright and related rights.

E. **Spam**

1. The Governments of Japan and the United States share concern about spam, which has become a worldwide problem for businesses and consumers, as well as in the Information and Communications Technology sector.
2. The United States Government will continue to pursue a multifaceted approach to combating spam, including vigorous enforcement of the CAN-SPAM Act, public private partnerships, promoting industry-led technical solutions, international collaboration (including enforcement cooperation), and consumer education.
3. The Federal Trade Commission (FTC) recently submitted a report to Congress evaluating the effectiveness of the CAN-SPAM Act. As of the date of the report, which was submitted in December 2005, the FTC, the Department of Justice, state Attorneys General, and ISPs had brought more than 50 cases under the CAN-SPAM Act since it went into effect on January 1, 2004. In addition to alleging violations of the CAN-SPAM Act, the FTC can also employ the FTC Act, which prohibits unfair or deceptive acts or practices in or affecting commerce, in its cases against spammers.

4. The FTC report to Congress, *Effectiveness and Enforcement of the CAN-SPAM Act*, is available at <http://www.ftc.gov/reports/canspam05/051220canspamrpt.pdf>.
5. The Government of the United States will continue to explore and consider measures to combat spam with the Government of Japan.

#### IV. MEDICAL DEVICES AND PHARMACEUTICALS

- A. **Regular Meetings with Japanese Companies Operating in the United States:** The U.S. Food and Drug Administration, Department of Health and Human Services (FDA/HHS), will continue to provide opportunities for meetings with Japanese companies operating in the United States. Japan led the world in visits to FDA/HHS in USFY2004 through the international visitor program (22 delegations) and was second in USFY2005 with 19 delegations. In the first half of USFY2006, FDA/HHS hosted 12 delegations from Japan.
- B. **Facilitation of Worldwide Simultaneous Development:** The Department of Commerce will continue to encourage U.S. industry to work with Japanese regulatory authorities to facilitate worldwide simultaneous development of pharmaceuticals, including in Japan.
- C. **Clarification of FDA's Inspection Policy:** FDA/HHS has provided explanations of details concerning its inspection policy and procedures through its website at [www.fda.gov/ora/inspect\\_ref/](http://www.fda.gov/ora/inspect_ref/). FDA/HHS inspections in Japan are concerned only with products destined for the United States, and not for products destined for the Japanese market. The Japanese company decides which products it wishes to market in the United States, thus choosing the focus of the inspection.
- D. **Observance of Time Period of Consultation on Clinical Trials for Investigational Device Exemption:** Regarding the Government of Japan's request to the Government of the United States that the time period of consultation on clinical trials stipulated in the Guidance on Investigational Device Exemption should be observed, both governments will continue to discuss this issue in the ongoing bilateral discussions between MHLW and FDA/HHS.
- E. **Clear Criteria on Medical Device Classification:** Regarding the Government of Japan's request to the Government of the United States to clarify the criteria on classification of attachments for medical devices and to enable manufacturers to make their own judgments on classification, both governments will continue to discuss this issue in the ongoing bilateral discussions between MHLW and FDA/HHS.
- F. **Acceleration of Third-Party Review of Pre-market Notifications:** Regarding the Government of Japan's request to the Government of the United States to stipulate the evaluation period of third-party reviews of pre-market notifications of medical devices, both governments will continue to discuss this issue in the ongoing bilateral discussions between MHLW and FDA/HHS.



- G. **Ultrasound Data for 510 (k) Submission of Endoscopic Ultrasonography:** Regarding the Government of Japan's request to the Government of the United States to revise the guidance and to confine the data attached to 510(k) submissions of endoscopic ultrasonographies only to typical data for the purpose of reducing the burden of applicants, both governments will continue to discuss this issue in the ongoing bilateral discussions between MHLW and FDA/HHS.
- H. **Clear Criteria for Application Categories:** Regarding the Government of Japan's request to the Government of the United States to clarify the criteria for application categories for post approval changes of medical devices after Pre-Market Approval for the purpose of enabling applicants to estimate the necessary time and cost beforehand, both governments will continue to discuss this issue in the ongoing bilateral discussions between MHLW and FDA/HHS.

V. **FINANCIAL SERVICES**

- A. **Registration Requirements for Foreign Issuers in Case of Business Reorganization:** Under Rule 145 of the Securities Act of 1933 (1933 Act), an offer or exchange of securities as part of a business combination – merger, consolidation, reclassification of securities or a transfer of corporate assets – is considered an offer and sale of securities. If the number of security holders involved precludes reliance upon other exemptions from registration, the securities exchanged as part of the transaction are required to be registered with the SEC under the 1933 Act. In 1999, the U.S. Securities and Exchange Commission (SEC) adopted Rules 800 and 802 under the 1933 Act, which exempts from registration requirements offers of securities as part of a business combination where the acquiring company and the target company are both foreign companies, and where U.S. residents hold less than 10 percent of the shares of the target company.
1. SEC staff believe that there is a sound basis for the SEC registration requirement. A decision to acquire securities in exchange for securities already owned is as much an investment decision as a decision to acquire securities by paying cash. Respect for investor protection concerns and a national treatment regime would not warrant a registration exemption for transactions covered by this rule (Rule 145).
  2. When the SEC adopted Rules 800 and 802 under the 1933 Act, as well as a similar Rule 801 exemption for foreign companies' rights offerings, the SEC carefully considered the level of U.S. ownership that was desirable and appropriate for purposes of these exemptions and in the interest of investor protection. SEC staff believe that, at or below the 10 percent level, U.S. holders' interests are best served by being able to participate in, rather than be excluded from, the securities transaction, even though they do not receive the full protections of the U.S. federal securities laws.
  3. Finally, Rules 800 and 802 are non-exclusive safe harbor exemptions. Even above the 10 percent level of U.S. ownership, more tailored relief has been

adopted that addresses conflicting regulatory mandates and offering practices. Accordingly, Japanese companies engaged in transactions that fail to meet, or have difficulty in determining compliance with, the 10 percent test (which is a threshold required in connection with the specific transaction, not an ongoing requirement) are encouraged to raise specific concerns with SEC staff to determine if tailored relief is warranted.

- B. Regulations on Sales and Offers of Foreign Investment Trusts:** Although, by its terms, Rule 7d-1 promulgated under the Investment Company Act of 1940 (Company Act) applies only to Canadian investment companies, the SEC historically also has issued 7(d) orders permitting registration under the 40 Act to non-Canadian foreign investment companies if they met the conditions of Rule 7d-1. For example, between 1954 and 1973, the SEC issued section 7(d) orders to investment companies from Canada, Australia, Bermuda, South Africa, and the United Kingdom. In each of these orders, the applicant agreed to comply with the conditions of Rule 7d-1 as a prerequisite to receiving its section 7(d) order. In some instances, the SEC has granted limited exemptive relief from Rule 7d-1. For example, in 1979, the SEC permitted a Canadian investment company to maintain its Japanese portfolio securities in the custody of a Japanese branch of a United States bank, which otherwise would have violated Rule 7d-1 (see Templeton Growth Fund, Ltd., Investment Company Act Release Nos. 10628 (March 13, 1979) and 10657 (April 11, 1979)).
1. Given the other avenues available, SEC staff believes that it is neither useful nor realistic to seek extension of Rule 7d-1 to Japanese funds or to propose changes in the substantive requirements of this rule. Under Section 7(d), the SEC is required to make a rigorous affirmative finding that investors in the foreign fund have enforceable protections equivalent to a U.S. fund. In actuality, there are very few funds that have met the requirements of Rule 7d-1 and the SEC has not issued any Section 7(d) orders for at least a quarter century. The SEC staff has no plans to recommend modification or extension of Rule 7d-1
  2. Section 7(d) does not operate on an exclusive basis to bar access to the U.S. market. It is possible for foreign sponsors to organize and register a U.S. mirror fund or a U.S. “feeder” fund that invests in a foreign “master” fund. Moreover, when Congress amended the 1940 Act in 1996, it adopted Section 3(c)(7), which permits domestic and foreign funds to operate on an exempt basis in the United States if they restrict offers and sales of their securities to “qualified purchasers.”
  3. In so far as the Government of Japan’s concerns are based upon the related issue of rules applicable to exchange-traded funds (ETFs), it should be noted that if a foreign sponsor were to organize and register a U.S. ETF under the 1940 Act, such an ETF would be eligible to apply for the same types of exemptive relief that SEC staff has provided for U.S. ETFs in order to facilitate their operation. In this respect, the criteria that the SEC staff must consider in granting exemptions for funds registered under the Act are not the same as the rigorous finding that is

required of the SEC under Section 7(d) in order to permit registration of a foreign fund.

- C. **Qualification of Financial Holding Companies:** Until recently, the United States, like Japan, restricted affiliations between commercial and investment banks. In the Gramm-Leach-Bliley Act, the Congress determined to lift these restrictions but only for those organizations whose U.S. depository institution subsidiaries meet very high prudential standards with respect to capital and management. Organizations that qualify for the liberalization are known as financial holding companies (FHCs). A foreign bank may become an FHC if the bank meets prudential criteria that are comparable to the prudential standards applicable to the U.S. bank subsidiaries of U.S. bank holding companies that are FHCs, giving due regard to the principle of national treatment and equality of competitive opportunity. The standards are applied to all foreign banks on a nondiscriminatory basis. Factors that may be taken into account in determining comparability of capital include the foreign bank's composition of capital, accounting standards, long-term debt ratings, reliance on government funding, and other factors that may affect analysis of capital. As has been previously noted, no one factor is determinative. More than 30 foreign banks are FHCs. The Government of the United States recognizes that many Japanese major banks have made progress in reducing the level of non-performing loans. The Government of the United States welcomes applications for FHC status by any foreign financial institutions that meet these prudential criteria.
- D. **Deregulation of Investment into Initial Equity Public Offering by Foreign Investment Trusts:** The National Association of Securities Dealers (NASD) Rule 2790 generally prohibits an NASD member from selling IPO shares to any account in which a "restricted person" has a beneficial interest ("restricted person" means, NASD members or other broker-dealers, broker-dealer personnel (including officers, directors, employees or agents of the broker-dealer), finders and fiduciaries (including attorneys, accountants or financial consultants to the managing underwriter and their family members), portfolio managers, certain persons owning a broker-dealer, and, in the case of each of the above persons, their immediate family members). U.S. registered investment companies are exempt from this prohibition. The Rule also includes a limited exemption for foreign investment companies, whereby such funds may participate in IPOs if no person owning more than 5 percent of the shares of the investment company is a restricted person. Foreign funds must also provide a written representation that all purchases of new issues are in compliance with the Rule. The purpose of the Rule is to ensure that the benefits of IPOs flow to the public and not to securities insiders who might use their position to obtain shares in new issues to the disadvantage of the general investing public.
1. The 5 percent limitation for foreign funds is prudentially based and is intended to prevent the circumvention of Rule 2790 by restricted persons who might seek to use a foreign investment fund to purchase IPO securities. Similar conditions are not imposed on domestic investment companies because such funds are subject to the U.S. regulatory regime, which includes, certain prohibitions on related party transactions.

2. Because of the inherent difficulties in assessing the comparability of a foreign jurisdiction's regulatory regime and to discourage U.S. investment companies from circumventing applicable rules by interposing a foreign fund, NASD determined that it was necessary to impose the additional conditions on foreign funds.
3. SEC staff understand that NASD intends to continue to consider the concerns raised regarding the 5 percent limitation on foreign funds and intends to have further discussions with industry regarding the rule and as to whether amendments are appropriate.