

**FOURTH REPORT TO THE LEADERS ON THE  
U.S.-JAPAN REGULATORY REFORM AND COMPETITION POLICY INITIATIVE  
November 2, 2005**

President George W. Bush and Prime Minister Junichiro Koizumi established the Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) in June 2001. Now in its fourth year, the Initiative is intended to promote economic growth by focusing on sectoral and cross-sectoral issues related to regulatory reform and competition policy.

Consistent with seeking to achieve tangible progress and the principle of two-way dialogue, the Governments of the United States and Japan exchanged detailed regulatory reform recommendations in October 2004. These recommendations provided the basis for extensive discussions between the two Governments for meetings of the High-Level Officials Group and the Working Groups established under this Initiative. These Groups met throughout the year to discuss reforms in key sectors and areas such as telecommunications, information technologies, intellectual property rights, energy, medical devices and pharmaceuticals, competition policy, transparency and other government practices, privatization, legal system reform, commercial law revision, distribution, consular affairs, and trade and investment-related measures. As in previous years, several of the Working Groups received input from private sector representatives, who made presentations and provided their valuable expertise, observations, and recommendations on important issues taken up under this Initiative.

The Government of Japan has taken a series of regulatory reform measures over the past year, including the adoption by Cabinet Decision in March 2005 of its revised Three-Year Program for the Promotion of Regulatory Reform. The Government of the United States welcomes this decision and the efforts by the Council for the Promotion of Regulatory Reform to improve the regulatory environment in Japan. The Government of the United States also continues to appreciate the work of the Headquarters for Promotion of Special Zones for Structural Reform to promote deregulation through the Special Zones. In addition, the United States and Japan are placing a growing focus on cooperating to strengthen intellectual property rights protection and enforcement in the region and around the world. The two Governments affirm their determination to continue to increase this cooperation in bilateral, regional, and multilateral fora.

The salient regulatory reforms and other measures by both Governments that relate to the work under the Regulatory Reform Initiative are set out in this Report to the Leaders. (Financial services measures taken up in the Financial Dialogue are also included.) The two Governments welcome the measures specified in this Report and share the view that these measures will improve market access for competitive goods and services, enhance consumers' interests, increase efficiency, and promote economic activity.

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 addition, the numbers of subscribers of third generation mobile phone and that of subscribed IP telephony numbers exceeded 30 million and 8 million respectively as of March 2005.
2. The Ministry of Internal Affairs and Communications (MIC) has been conducting a competition evaluation of various telecommunications markets since FY2003 in order to accurately understand the status of competition in the telecommunications market, which is becoming increasingly complex as a result of the rapid evolution of Internet Protocol (IP) and broadband technologies and services.
3. MIC published the result of its evaluation of the “Internet access” market in June 2004 after conducting a public comment procedure. According to this market evaluation, based on the circumstances including the current regulatory regime, there has not been any concern about the exercise of market power by either a single carrier or collusive plural carriers in ADSL and FTTH on detached housing and collective housing markets.
4. This year, MIC reevaluated several broadband services such as ADSL, FTTH and cable TV internet services in the area of “Internet access,” and newly evaluated IP telephony market (a major form of application of broadband services) and mobile communications markets (including the cellular phone market, which is composed of three company groups). MIC published the result of the evaluation in July 2005 after conducting public comment procedures.

**B. Fixed Interconnection**

1. The evolution of broadband services, accompanied by the spread of IP telephony, as well as the diffusion of mobile phones, has resulted in a rapid decrease in the volume of traffic over traditional fixed phone lines. The annual rate of decrease over the past 2 years has been around 15 percent in terms of unit communications time. In addition, the environment surrounding the telecommunications market is rapidly changing; one recent example is the start of direct fixed line telephone

services by competitive carriers that use the “dry copper” loops of the incumbent carriers.

2. Taking into consideration these environmental changes in the telecommunications market, the Information and Communications Council submitted the proposal “A Calculation Method of Fixed Interconnection Rates from FY2005 Onward.” The proposal included an evaluation of a new calculation model that could contribute to the reduction of related costs as well as the phased elimination of non-traffic sensitive (NTS) costs over a five-year period.
3. Based on this proposal, MIC revised the related ministerial ordinances in February 2005 for the revision of the calculation method for interconnection rates that became applicable in and after FY2005. Revision of the LRIC model reduced the interconnection-related costs by 11.8 percent. This, together with the reduction of NTS costs, compensated for a significant decrease in traffic (20.2 percent for IC switches and 16.3 percent for GC switches, comparing FY2004 with FY2003), and curbed new interconnection rate increases to 14.9 percent for IC and 2.7 percent for GC.
4. The revised model will be in effect for three years. MIC will continue to conduct any further deliberations on either the revision of the model or its replacement in a transparent manner.
5. In December 2004, the Information and Communication Council established the “Universal Service Working Group” to conduct the review of the universal service fund mechanism. The draft report of the working group’s proposal was released for public comment in July 2005. The Government of Japan and the Government of the United States reaffirmed their continued intentions to maintain any universal service mechanism in line with WTO Reference Paper commitments.

### **C. Mobile Communications**

1. NTT DoCoMo’s interconnection rates have been reduced over the last four years by approximately 25 percent, to levels currently among the lowest in developed countries that employ calling-party-pays systems. The rates filed in March 2005 were reduced by 3.4 percent. Telecommunications carriers with Category II-designated telecommunications facilities (mobile networks) continue to be required to notify MIC of and publicize interconnection tariffs.
2. With regard to spectrum for mobile services, a plan for IMT-2000 frequency arrangement in the 800MHz band was decided through transparent procedures, such as solicitation of public comments and open discussions among interested parties and experts in the “Study Group to Examine Expanded Use of Frequency Bands for Mobile Services.”

3. To further promote competition in the mobile communications market and effective use of spectrum, MIC drafted a license policy for the 1.7GHz band and the 2GHz band that addressed issues such as eligibility for and numbers of new licenses. MIC solicited public comments on the draft policy and consulted the Radio Regulatory Council for its recommendations. The final policy, decided in August 2005, gave priority to new market entrants while also coping with the spectrum congestion of incumbent carriers under its licensing criteria for these bands. Spectrum allocation will be completed by the end of this year, based on the applications received by September 30, through fair and transparent procedures.

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

1. The Telecommunications Working Group of the Regulatory Reform Initiative heard views from private sector experts on mutual recognition systems and next generation wireless technology.
2. In December 2004, the Information and Communications Council released a partial report proposing technical conditions for high-power passive tag systems using the 950MHz band. Taking into consideration the proposal and other discussions, MIC made necessary adjustments to related ministerial ordinances in April 2005. With regard to the active tag system using the 433MHz band, the discussions at the Information and Communications Council will continue based on the results of experimental trials on the possibility of its shared use with amateur radio. MIC issued an experimental radio stations license for these experimental trials in July 2005. When the Council releases a draft report on these discussions, MIC will conduct public comment procedures.
3. With a view toward the development of a ubiquitous network society, MIC established the “Study Group for Wireless Broadband Promotion” in November 2004. The study group compiled an Interim Report in April 2005, and invited submissions on practical wireless broadband systems. The method to facilitate frequency reallocation for wireless broadband systems is under consideration in this study group.
4. The “Study Group on Policies Concerning the Effective Radio Spectrum Use” decided in its final report to recommend not charging spectrum user fees to license-exempt radio systems that do not have exclusive use of bandwidth.

#### **E. Deregulation of Network Construction**

1. To accommodate urgent construction of fiber-optic networks by telecommunications carriers that could not have been foreseen at the beginning of a fiscal year, the Ministry of Land, Infrastructure and Transport (MLIT) has been undertaking necessary coordination among relevant parties including road administrators and telecommunications carriers approximately every 3 months.

Based on this coordination, MLIT has been easing the relevant restrictions on road construction in winter and around the end of a fiscal year, to the extent compatible with not seriously disrupting road traffic. These measures will be maintained until the end of FY2005.

2. With regard to directly controlled national roads, MLIT has, since FY2001, enabled electronic application for the use of rights-of-way nationwide. As for the other national roads and roads controlled by local authorities, MLIT encouraged these authorities to enable electronic application procedures. MLIT established and publicized the basic specifications of a standard system for local authorities.

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

1. Following several meetings, MIC and FCC reached a common view on respective procedures suitable for mutual recognition of telecommunications equipment and equipment subject to electro-magnetic compatibility (EMC) requirements. With regard to telecommunications equipment, the Governments of Japan and the United States expect to start formal negotiations in November 2005 with a view toward conclusion of those negotiations in early 2006, if feasible.
2. Regarding EMC, the Government of the United States confirmed that it is prepared to work with Japan 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.

- G. **Network Channel Terminating Equipment (NCTE):** The Government of Japan will invite public comment regarding the proposed abolishment of the streamlined procedures of the 1990 Exchange of Letters on Network Channel Terminating Equipment (NCTE) (“the 1990 Letters”) which were described in the Third Report to the Leaders. Unless sufficient evidence demonstrating the continued need for these revised procedures is submitted from the interested parties through public comments, the 1990 Letters will cease to be applied in and after FY2006.

## II. **INFORMATION TECHNOLOGIES**

- A. **Removing Regulatory and Non-Regulatory Barriers:** Japan has made significant progress in the area of IT and has realized remarkable achievements. Internet service in Japan, for example, is now among the fastest and most affordable in the world, and Japan’s e-commerce market has grown to become the second largest in the world after the United States. Japan will continue to strive to foster a regulatory environment that further promotes the utilization of IT, including e-commerce.

1. Online Services: The Government of Japan will continue to remove barriers in existing laws and regulations that hinder e-commerce, such as requirements for face-to-face or paper-based transactions and other hindrances to e-commerce and

online services; and amend laws and regulations as necessary to allow electronic notifications and transactions in sectors in which they are currently barred. The Government will, for example, start the partial operation of “One-Stop Service” for Motor Vehicle Registration in December 2005 by providing this new service for registering new vehicles in some locations. “One-Stop Service” will be expanded to all procedures related to vehicle registration in all locations on an on-line basis by 2008.

2. Technology Neutrality: The Government of Japan shares 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. While it is, however, sometimes inevitable to employ specific technologies under certain limited circumstances, the Government of Japan continues its efforts to maintain technology neutrality to the extent appropriate and practicable, as it has done with its “Law Concerning Electronic Signatures and Certification Service” with respect to the definition of electronic signatures (which avoided excessive dependence on any specific technology).
3. Private Sector Partnership and International Harmonization: The Government of Japan understands that the private sector is a key player in developing and implementing its e-Japan policies. Based on this principle, the “e-Japan Priority Program-2004” articulates the need to cultivate an environment that facilitates smooth market operations through, for example, promotion of free and fair competition and revision of related regulations that can fully activate the potential of the private sector. The Government of Japan will also continue to develop legal frameworks without excessive regulation and impediments to e-commerce, and seek to harmonize these frameworks internationally.
4. e-Document Law: To reduce costs in the private sector, the Government of Japan implemented the e-Document Law in April 2005.
  - a. The Government of Japan worked to ensure that the e-Document Law is implemented in a manner that strikes a balance between the need for cost reduction in the private sector and effective legal requirements for paper storage. The Government of Japan also endeavored to ensure consistency among all relevant regulations (ministerial ordinances) for the law. The IT Strategic Headquarters (ITSH) has played a major role in this regard by, for example, managing the work schedule for the establishment and revision of relevant regulations by individual Ministries and Agencies.
  - b. Relevant Ministries and Agencies also took several measures, such as the use of public comment procedures, to incorporate private sector input into the development of the implementing regulations for the e-Document Law.

5. Coordination of IT Policy:

- a. As is clearly stated in the “e-Japan Priority Policy Program-2004,” the ITSH has been closely cooperating with the Council for the Promotion of Regulatory Reform (CPRR) and the Headquarters for the Promotion of Regulatory Reform in making and implementing policies regarding regulatory reform in the IT area. The ITSH will continue close coordination with these institutions in order to maximize the benefits of Japan’s IT policies.
- b. The ITSH appointed specialists from the private sector as members of the Expert Committee. In this course, the ITSH paid attention to the maintenance of neutrality and transparency of this Committee, and chose private sector experts who could advise the ITSH from a wide range of visions that reflect the current globalized IT society. To further expand that range of visions, the Government of Japan will actively seek input from experts, including experts from non-Japanese entities, as it undertakes subsequent evaluations of e-Japan. The Expert Committee on IT Strategy Evaluation has been actively evaluating progress achieved in pursuit of Japan’s IT policy goals including the “e-Japan Priority Policy Program-2004” based on the PDCA-cycle (“Plan Do Check Act” cycle) method. The results of the ongoing evaluation are reported to the ITSH. Moreover, in the decision of “e-Japan Strategy,” “e-Japan Strategy II,” and “e-Japan Priority Policy Program - 2004,” the ITSH sought opinions from parties concerned including those of the private sector, by employing the public comment procedure, and will continue to do so for developing future IT strategies.
- c. The Inter-Ministerial Task Force (*renraku kaigi*) on IT, which consists of the Deputy Vice-Minister for Management of relevant Ministries and Agencies, was established in February 2004 to promote inter-ministerial cooperation. Individual task forces have also been working under the ITSH’s initiative for important policies that involve more than one Ministry and should be pursued under closer inter-agency coordination. The ITSH will continue to promote the IT policy in close cooperation with relevant Ministries and Agencies.

**B. Strengthening the Protection of Intellectual Property Rights:** Through the Subcommittee on Copyright under the Council for Cultural Affairs, the Government of Japan is conducting an extensive review of the Japanese Copyright Law to determine changes required to address issues stemming from the burgeoning use of digital technology.

1. Copyright Term Extension: The Government of Japan will continue its deliberations on extending the terms of protection for copyright, 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 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 decrease the burden on right holders, including statutory damages for infringement, and will reach a conclusion of its review in this regard by FY2007.
3. Protection of Digital Content: To strengthen the protection of digital content:
  - a. The Governments of Japan and the United States will continue to exchange information on improving protection of digital content, including software and other intellectual property assets, on government-supported IT resources as necessary.
  - b. 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. The Government of Japan continues to observe the status of implementation of the Law. Currently, this includes periodical circulation of a questionnaire to stakeholders to help understand the effectiveness and the adequacy of the Law.
  - 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.
  - d. The Government of Japan has ensured the right of making available, in compliance with the WCT and WPPT, to address the infringement of copyright and neighboring rights in works and phonograms that are uploaded onto peer-to-peer networks. 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.
  - e. The Government of Japan has made efforts to render its interpretation of the scope of protection for a "temporary copy" known through appropriate measures. In addition, the Government of Japan will continue to make efforts to clarify its interpretation of the scope of "temporary copy" protection through appropriate measures.



- f. The Governments of Japan and the United States will continue to discuss issues related to improving technological protection measures.
  - g. The Governments 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.
- 5. Appropriate Scope for Education Exception 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:
  - a. 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. To further discussion on several important issues on which IPSH did not reach final conclusions, IPSH established three task forces in October 2003: (1) Task Force on Enhancement of IP Protection; (2) Task Force on Patentability of Medical Treatment Inventions; and (3) Task Force on Content Business. The law provides that the IPSP shall be reviewed and revised at least once a year. Consistent with this, IPSH finalized and published the IP Strategic Program 2005 on June 10, 2005.
  - b. 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 decided by the Cabinet. 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. 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 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 their opinions when the IPSH deems it necessary.

7. U.S.-Japan Cooperation to Improve Intellectual Property Rights Protection:
- a. To combat the serious and growing problem of the global trade in pirated and counterfeit goods, both the United States and Japan have recently established major new initiatives. In October 2004, the United States launched the Strategy Targeting Organized Piracy (STOP!), and in June 2005, Japan launched the “Intellectual Property Strategic Program 2005.”
  - b. In addition to establishing their own initiatives in this area, the United States and Japan have been and will continue to closely cooperate on strengthening intellectual property rights protection and enforcement. Along with cooperating multilaterally, the two Governments, for example:
    - (1) Held bilateral meetings in November 2004 and April 2005 to promote IPR protection and enforcement in Asia and around the world;
    - (2) Co-sponsored the APEC Anti-Counterfeiting and Piracy Initiative, which was endorsed at the meeting of APEC Ministers Responsible for Trade in June 2005 in the Republic of Korea; and
    - (3) Discussed under the Regulatory Reform Initiative ways to cooperate to combat piracy of digital content.
  - c. The Governments of Japan and the United States will continue to cooperate in bilateral, regional, and multilateral fora to promote greater protection for intellectual property rights world wide.

**C. Promoting and Facilitating Public and Private Sector Use of E-Commerce**

- 1. Privacy: Relevant Ministries and Agencies of the Government of Japan have introduced new guidelines and/or revised existing ones concerning the implementation of the Act on the Protection of Personal Information (Act), which fully went into effect on April 1, 2005, in a manner intended to ensure their effectiveness.
  - a. 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.
  - b. Relevant Ministries and Agencies are to provide support for industry organizations that publish voluntary guidelines for personal information

protection. Those voluntary guidelines are expected to contribute to the proper handling of personal information in the private sector.

- c. The Government of Japan regards it essential to ensure transparency, respect voluntary efforts by the private sector, and promote better understanding of the implementation of the Act, as demonstrated by the following:
    - (1) On March 23, 2005, the Cabinet Office, the Financial Services Agency, the Ministry of Internal Affairs and Communications (MIC), the Ministry of Economy, Trade and Industry (METI) and the Ministry of Health, Labour and Welfare sent their experts to participate in a seminar for U.S. and Japanese enterprises on the Act, which provided more than 300 participants with a valuable opportunity to better understand its implementation.
    - (2) The Government of Japan believes that it is important that relevant Ministries and Agencies implementing the Act publicly provide information on enforcement and corrective actions.
    - (3) As noted in the Basic Policy, the Cabinet Office shall examine the enforcement status of the Act approximately three years after it fully goes into effect and will take necessary measures based on the results. Relevant Ministries and Agencies regard it important to take necessary measures to ensure the appropriate treatment of personal information by the implementation guidelines. For example, METI plans to conduct annual reviews of the effectiveness of its implementation guidelines and make any necessary changes to seek consistency throughout the government.
2. Promotion of Alternative Dispute Resolution: The Governments of Japan and the United States recognized in the 2004 Report to the Leaders that accessible and effective Alternative Dispute Resolution (ADR) mechanisms are requisite to the successful functioning and development of e-commerce. The Government of Japan will ensure that the implementation of the “Law Concerning the Promotion of the Use of Alternative Dispute Resolution Procedures” (ADR Law) does not hinder the use of ADR in e-commerce disputes either within Japan or in the cross-border context. As such:
- a. Under the ADR Law, parties will be allowed, as a general matter, to determine the rules, processes, and standards to be applied in individual ADR proceedings, including those concerning e-commerce. The Government of Japan will ensure that the implementing ordinances and guidelines to the ADR Law are designed to promote online dispute resolution and accommodate the cross-border nature of e-commerce.

- b. The Government of Japan will monitor closely, once the ADR Law comes into effect, the effects of the ADR Law on ADR proceedings involving cross-border or e-commerce disputes and take action without delay to remedy any problems or impediments to such ADR proceedings that come to light.
3. Network Security: Under the Japan-U.S. Joint Statement on Promoting Global Cyber Security adopted on September 9, 2003, the Governments of Japan and the United States recognized that the increasing number of cyber attacks and the interdependence of global information networks place responsibility on all nations to respond to the challenge of securing critical information infrastructures. The Government of Japan is working to raise the level of information security in Japan, both in government and private sectors. The Governments of Japan and the United States reaffirm their recognition that critical infrastructure protection is a shared responsibility of the public and private sectors, particularly because the vast majority of critical infrastructure is owned by the private sector.
- a. In an effort to strengthen its ability to develop and implement appropriate and uniform information security policies, the Government of Japan in December 2004 decided to proceed with establishment of the Information Security Policy Council (Council) and the National Information Security Center (NISC) within the ITSH. The NISC became operational in April 2005, and the Council was set up in accordance with the decision of the ITSH in May 2005. The Government of Japan will make utmost effort to provide these units sufficient resources to fulfill their objectives of enabling government-wide coordination and creating effective information security policies.
  - b. The Government of Japan currently is formulating details of its draft “standards for information security measures (standards for measures)” for its central government computer systems. The first stage of these standards for measures, released September 15, 2005, focuses on setting common basic measures among Ministries and Agencies, such as password usage and virus prevention. Following the establishment of these common basic standards for measures, the Government of Japan is currently developing more sophisticated standards for measures for securing central government computer systems. In the June 2004 Report to the Leaders, the Government of Japan confirmed that these standards for measures would be, where appropriate, open (non-proprietary) and consistent with standards developed by voluntary standard bodies constituted upon consensus in industry. Further regarding these forthcoming standards for measures, the Government of Japan:
    - (1) Acknowledges the interdependent nature of government and private sector computer systems, and that private sector firms

supply the majority of the IT infrastructure to support government computer systems.

- (2) Acknowledges that it is beneficial for the Government to seek technical advice from a wide range of interested parties, especially to obtain input on technical feasibility or when there are a variety of measures from which to choose. This process can help create the best possible and most technically feasible standards for measures. Further, if the Government of Japan enhances its security measures in a transparent manner, they can serve as useful references for the private sector.
  - (3) Recognizes that comments from a wide range of interested parties will be useful in formulating these standards for measures. Therefore, the NISC will continue to consider appropriate ways to invite public input into its process. In particular, in those areas where its standards for measures will impact vendors, contractors, or other private entities, the Government of Japan believes it will be critical to obtain input as widely as possible, from all interested domestic and foreign parties. The NISC commenced a review and public comment process on a draft of these standards for measures on October 17, 2005.
- c. In accordance with the “IT Policy Package 2005,” which the ITSH issued in February 2005, the Government of Japan will promote the increased use of information security measures in the private sector. Recognizing that voluntary best practices can be more easily revised, the Government of Japan will work in conjunction with the private sector to develop and disseminate voluntary best practices for information security in, and will encourage the voluntary acceptance and adoption of such information security measures by, the private sector during FY2005 and beyond.
  - d. The Governments of Japan and the United States will continue to share information and experiences to improve best practices regarding information security.
4. Spam: The Governments of Japan and the United States are concerned with unsolicited commercial email, or spam, which is generally recognized as a burden for consumers and businesses alike. Spam is also increasingly associated with various forms of online fraud and the dissemination of malicious code, such as viruses and phish. The Government of Japan has been actively working on anti-spam measures including the enforcement of the Law on Regulation of Transmission of Specified Electronic Mail (the Anti-Spam Law) which passed in April 2002 and came into force in July 2002. Based on the discussions of the Study Group on a Framework to Handle Spam, which has been meeting regularly since October 2004 at MIC, an amendment bill to the Anti-Spam Law that

includes the introduction of direct penalty was submitted to the Diet in March 2005 and passed in May 2005.

- a. The Government of Japan will further promote the international anti-spam activities in close cooperation with the United States.
- b. The Government of Japan also recognizes the importance of respecting the private sector's voluntary activities to develop innovative technologies including authentication technology in combating spam, and will work together with the private sector on policy development in combating spam, which is the view shared by the Government of the United States.

#### D. **Promoting Procurement Reforms for Information Systems**

1. Promoting Implementation of Reforms: In December 2004, the results of a "follow-up survey" of progress made by Ministries in FY2003 in implementing the reforms outlined in their memorandum of agreement on government procurement for information systems were published on MIC's website.
  - a. Recognizing the importance of consistent, complete, and timely implementation of the memorandum's reforms, the Government of Japan's Inter-Ministerial Task Force for Information Systems Procurement (*renraku kaigi*) will direct all Ministries to fully implement them as soon as possible.
  - b. All Ministries and Agencies will enhance their efforts to implement by the end of FY2005 items in Section 2 of the memorandum concerning a review of rules for participation in bidding. This will expand opportunities for small and medium-sized enterprises and foreign firms to engage in information systems procurement.
  - c. In accordance with the "IT Policy Package 2005," METI will formulate "Procurement Skill Standards" by the end of FY2005 to enhance competency in this area. This is an important contribution to the goal identified in Section 3 of the memorandum concerning the improvement of training for procurement officers.
2. Measuring Progress on Implementation of Reforms: The 2004 follow-up survey of progress made in implementing the memorandum's reforms provided useful data indicating the overall pace and scope of individual Ministries' work in this area that the 2003 follow-up survey's results did not include. In April 2004, the Government of Japan created an online database (<http://cyoutatujirei.e-gov.go.jp/>) that includes information about awards of procurement contracts for information systems.

- a. The Government of Japan plans to conduct another annual follow-up survey. The Inter-Ministerial Task Force will discuss the format and contents of the survey.
- b. To complement the results of follow-up surveys and support efforts to accurately evaluate progress being made on implementing reforms in the memorandum, the Government of Japan will ensure that all Ministries regularly contribute all necessary information about specific procurement cases to the online database for information systems procurement.
- c. When the quantity and quality of information in the database reach appropriate levels, the Government of Japan will analyze this information and publish statistics that help identify trends in information systems procurement.
- d. The Inter-Ministerial Task Force will continue to promote the use of the database by the public.

3. Evaluating and Enhancing the Effectiveness of Reforms:

- a. The Cabinet Secretariat posted “Japan’s Government Procurement: Policy and Achievements Annual Report (FY2004 version)” on its website in May 2005. This report provides responses to several questions and comments the Cabinet Secretariat has received related to procurement, and presents the results of a survey of suppliers the Cabinet Secretariat conducted in FY2004 to collect their opinions concerning the threshold used by Japan for the Overall Greatest Value Method (OGVM), including the threshold for computer products and services. To increase opportunities for interested parties to learn about and provide feedback on information systems procurement issues and reforms, the Government of Japan will change or increase the number of questions it includes in its survey of suppliers in the Cabinet Secretariat’s Annual Report on procurement that are related to these issues and reforms.
- b. Nearly all Ministries have set criteria for low-priced bidding investigations to discourage unreasonably low-priced bids. Ministries currently provide information about the results of these investigations to the Japan Fair Trade Commission and to MIC for inclusion in the information system procurement database.
- c. Ministries conducted 22 low-priced bid investigations in 2003. The Government of Japan will continue to work to ensure that measures intended to discourage unreasonably low-priced bids that are anticompetitive are utilized effectively.

4. Strengthening Reforms:

- a. As part of the CIO Council's "e-Government Plan," Ministries have been directed to conduct reviews of their work operations and "legacy" computer systems with the objective of replacing them or making changes to them that will help reduce costs and increase performance. Renovation feasibility studies for 36 of these systems were completed in FY2004, and the results of these have been posted on each Ministry's website (with the exception of those unsuitable for publication for security reasons). Ministries will develop optimization plans for their legacy systems by the end of FY2005 and implement these plans starting from FY2006. The CIO Council will continue to work to ensure that Ministries follow its instructions to conduct these reviews in a transparent manner and provide public comment periods for them before optimization plans are finalized. The CIO Council will also direct all Ministries to continue to discuss how contracting arrangements for legacy computer systems might be improved through appropriate use of contract unbundling, competitive bidding, multi-year contracts, and other measures.
- b. In 2003, CIO Aides were selected from among outside experts to assist Ministries in reviewing work operations and information systems and devise plans to improve them. To help Ministries function more efficiently and cost-effectively, the Cabinet Secretariat and all relevant Ministries will work to enhance the Aides' functions, as directed in the IT Policy Package 2005.
- c. The Inter-Ministerial Task Force will continue to work to ensure that Ministries publish the results of bidding on information systems procurement without delay after a contract is signed.

### III. ENERGY

- A. **Regulatory Authorities:** The Government of Japan has implemented some significant reforms of its electricity and gas sectors in order to develop a competitive energy market with expanded retail choice and opportunities for new market entry, consistent with the Basic Energy Policy Act's goals of ensuring a stable supply of energy and environmental protection. Japan's reform process is welcomed by the Government of the United States. Vigilant market oversight is necessary to ensure the effectiveness of these reforms in the creation of a fair, efficient, and stable energy market. The Government of Japan thus recognizes the importance of establishing an enforcement mechanism equipped with the necessary number of staff under clear rules of conduct with sufficient expertise, independence and budget resources to provide such oversight. In March 2005, METI established the Market Monitoring Subcommittee (hereinafter referred to as "the Subcommittee") under the Electricity Industry Committee (hereinafter referred to as "the Committee") as well as the Urban Heat Energy Subcommittee of the Advisory Committee for Natural Resources and Energy. The Subcommittee is to support METI's monitoring of liberalized electricity and gas markets as well as dispute settlement.



Membership of the Subcommittee will consist of external academic experts and the Subcommittee will operate in a manner that ensures independent recommendations.

**B. Public Input:** METI took important steps to ensure that the development of related ministerial ordinances and guidelines associated with implementation of Japan's electricity and gas reform was an open and transparent process. To further promote fairness and transparency in the decision making process, METI will continue to provide meaningful opportunities for public comment, and ensure that public comments are factored into the final rules.

1. Electricity: In early 2005, METI and the Japan Fair Trade Commission (JFTC) solicited and responded to public comments on the draft revision of Guidelines for Fair Power Trade.
2. Natural Gas: In the middle of 2004, METI and JFTC solicited and responded to public comments on the draft revision of Guidelines for Fair Gas Trade.

**C. Electricity:** The Electricity Utilities Industry Law (the "Electricity Law") was amended in June 2003, paving the way for a new electricity industry system. METI has also amended ministerial ordinances, resulting in expansion of retail choice to about 63 percent of the market (2.4 times the 2003 level) as of April 2005.

1. Fairness and Transparency in Transmission/Distribution:
  - a. *Neutral System Organization:*
    - (1) Based on the Electricity Law, METI designated the Electric Power System Council of Japan (ESCJ) as the Neutral System Organization (NSO) in June 2004 after reviewing proposed business plans, including information on its financial and technical potential. ESCJ is a limited-liability intermediate corporation that is to be neutrally administered by the general power utilities (GPUs), new entrants, and other network users, as well as academic experts. It also has an advisory council consisting of economic analysts, consumers, and media representatives.
    - (2) The NSO issued detailed rules pertaining to construction of network facilities, network access, system operation, and information disclosure, taking into account input from the Committee's final report and public comments. Each GPU also issued its own rules pursuant to the NSO rules.
    - (3) METI supervises the NSO in order to secure fairness and transparency of its decision making, and will issue orders or revoke the designation of the NSO if necessary to correct any inadequacies.

b. *Behavioral Regulation:*

- (1) Based on input from the Committee, including public comments submitted, METI will soon revise a ministerial ordinance in order to require separation of transmission/distribution segment accounts from other segments, and to provide for separation of accounts in an income statement.
- (2) METI revised the Guidelines for Fair Power Trade with JFTC in May 2005 in order to ensure effective information firewalls and the prohibition of discriminatory treatment pertaining to wheeling services. In addition, METI added Guidelines regarding fair competition between electricity and gas in response to recent concerns heard from industry, such as competition in the introduction/proliferation of co-generation systems and “all-electrification” projects.
- (3) If METI or JFTC finds that a GPU has performed an act in violation of the Electricity Law, the Antimonopoly Act, or the Guidelines, it will issue a stop or change order to the GPU to remedy the problem, and request discussions in the Subcommittee if necessary.

2. System Design for a New Electricity Market:

a. *Wholesale Electric Power Exchange:*

- (1) In the report “Framework of the Desirable Future Electricity Industry System” issued in February 2003, the Committee noted that the wholesale electricity market has an important role in the electricity market, although it would be private and voluntary.
- (2) The private Japan Electric Power Exchange (JEPX) was established in November 2003 and began trading in April 2005.

b. *Liberalization Schedule:*

- (1) As a result of the December 2004 amendment of the ministerial ordinance, the scope of retail liberalization was expanded in April 2005 to all customers using high voltage electric service of 50kW or greater.
- (2) Discussion of full retail liberalization, including household customers, will start around April 2007, taking into account the results of partial liberalization up to that time.

- (3) The Government of Japan has been publicizing the expansion of retail liberalization through public notices in newspapers and through leaflets.

3. Review of the Wheeling Services System:

a. *Balancing Rules:*

- (1) After considering public comments, METI relaxed the balancing rules in April 2005 so that a new entrant can choose a secondary fluctuation range of 3 to 10 percent, in addition to the primary fluctuation range of 3 percent. A new balancing support system was introduced in connection with the start of a new wheeling services system in April 2005, so that a new entrant can access customer demand data every 30 minutes. The data is collected and owned by the GPUs, using remote metering systems or other systems.
- (2) METI prepared ministerial ordinances and other regulatory texts in December 2004 in order to implement such measures.

b. *Abolition of Pancaking:* To facilitate nationwide electricity transactions through fair and transparent wheeling service charges, METI issued ministerial ordinances and other regulations in December 2004 in order to eliminate the “pancaking” problem and to introduce a new framework for network users to pay a uniform wheeling rate in the area they supply, wherever they generate. This reform was also implemented in April 2005.

c. *Clarification of Standards to Issue Orders to Change Rules of Wheeling Services:* METI clarified its standards and issued necessary regulations for implementing “change orders” in order to ensure an appropriate enforcement mechanism for network regulation.

4. Review of Regulatory Reform: The electricity market has changed since April 2005 with implementation of a series of new electricity industry reforms. The Cabinet decided on the “Three-Year Program for the Promotion of Regulatory Reform” on March 25, 2005. In accordance with this plan, METI will monitor market conditions and evaluate their impact by reference to a set of announced qualitative or quantitative criteria, taking into account the need for additional steps, such as additional regulatory reforms to ensure fairness, transparency, and competitiveness in the market. Such assessment criteria may include transactions on the wholesale power market, operations of the NSO, observance of behavioral rules, newcomers’ entry and competitive behavior between the GPUs.

D. **Natural Gas:** An amendment of the Gas Utilities Industry Law (the “Gas Law”) was approved by the Diet in June 2003 and entered into effect in April 2004. The scope of retail choice was expanded to consumers with an annual demand of 500,000 cubic meters and above in the Gas Law, expanding retail choice to about 50 percent of the market as of December 2004. METI has been developing, after notice and comment where appropriate, regulations associated with changes in the Gas Law, and implementing and enforcing these regulations.

1. Fairness and Transparency of Third-Party Access (TPA) to Pipelines:

- a. TPA rates: METI revised in September 2005 the Guidelines for Information Disclosure on Gas Rates in order to make the administrative process for approving rates more transparent and to make gas utilities accountable for the reasonableness of their charges.
- b. Accounting separation: METI established in October 2004 a ministerial ordinance for accounting separation that establishes requirements on how to separate the account of the gas transportation/distribution segment from that of other segments, as well as requirements for the publication of these separated accounts.
- c. Behavioral regulation: METI and JFTC jointly revised the Guidelines for Fair Gas Trade in August 2004 with new provisions that include requirements for information firewalls and the prohibition of discriminatory treatment of particular TPA users as stipulated in the Gas Law. If METI finds that a gas utility has performed an act contrary to the Gas Law, it will issue a stop or change order to remedy the problem. Similarly, if JFTC finds that a gas utility has performed an act contrary to the Antimonopoly Act, it will take action to remedy the problem.

2. Development of Pipeline Network: The Ministry of Land, Infrastructure and Transport issued a rule in October 2004 allowing pipelines to be buried at a depth of 1.2 meters instead of the previously required depth of 1.8 meters. This is expected to facilitate cost-effective enhancement of Japan’s gas pipeline network, and thereby allow greater competition.

3. Third-Party Access to LNG Terminals: As part of the August 2004 METI and JFTC joint revision to the Guidelines for Fair Gas Trade, an article about TPA to LNG terminals was newly added to promote non-discriminatory negotiations between LNG terminal owners and TPA users.

4. Review of Regulatory Reform: METI will monitor market conditions and evaluate the impact of the regulatory reform, by reference to qualitative or quantitative criteria such as an assessment of new entrants, the utilization of TPA regimes, the compliance with behavioral regulations, including the Guidelines for Fair Gas Trade, as well as from the viewpoint of the impact on the stability of

supply and safety. METI will make this evaluation taking account of the need for the implementation of regulations to ensure fairness, transparency, and competitiveness in the market, and in consultation with the Urban Heat Energy Subcommittee.

5. Further Expansion of Retail Choice: METI will amend the ordinance in a timely fashion in order to expand the scope of retail choice for consumers with an annual demand of 100,000 cubic meters and above from 2007. Whether and how to expand retail choice for household and small commercial users with an annual demand of less than 100,000 cubic meters will be determined in a timely manner. The monitoring of the market and the evaluation of the regulatory reform above-mentioned will be reflected in the detailed regulation design in expanding the scope of retail choice in 2007, as well as in consideration of further expansion of retail choice.

#### **IV. MEDICAL DEVICES AND PHARMACEUTICALS**

##### **A. Medical Device and Pharmaceutical Pricing Reform and Related Issues**

1. Reimbursement Pricing Reform: In March 2003, the Cabinet of Japan decided to review the reimbursement prices of medical devices and pharmaceuticals with a view to reducing the price differences between domestic and foreign markets and taking current market prices into account. In view of this decision, the Ministry of Health, Labour and Welfare (MHLW) will continue to implement reforms while recognizing the value of innovation. At the same time, it is important to ensure efficient, high-quality healthcare for Japanese patients and to encourage the development of better medical devices and pharmaceuticals. The Government of Japan is now tackling a fundamental reform of the medical insurance system. In April 2005, subcommittees under the Central Social Insurance Medical Council (*Chuikyo*) started a review of the pricing systems for pharmaceuticals and medical devices. Industry has been provided with opportunities to express views at *Chuikyo*, and *Chuikyo* will take those views into account. In FY2005, in order to expedite opportunities for the pharmaceutical industry, MHLW held a hearing on pricing reform in July rather than autumn as in previous years. MHLW will continue to provide industry, including U.S. industry, with meaningful opportunities to express views at *Chuikyo*. In FY2005, MHLW will ensure that reimbursement pricing is consistent with its recognition of the value of innovation. When determining reimbursement pricing policies, MHLW will pay attention to industry's views regarding the factors that increase the cost of doing business in Japan.
  - a. *Pharmaceuticals*:
    - (1) **Consideration of Additional Application Materials**: MHLW confirms that it will accept submission of any materials from an applicant in addition to the review report when selecting

comparators and premiums. MHLW also will send all submitted materials to members of the Drug Pricing Organization (DPO) and encourage them to consider those materials.

- (2) U.S. Government View: Regarding the Government of Japan's consideration of reforms in its reimbursement pricing system for pharmaceuticals, the Government of the United States noted its view concerning adoption of a manufacturer's suggested reimbursement price (MSRP) system and changes regarding the comparator method and the criteria of repricing based on market expansion.
- (3) Premiums: In FY2002, MHLW substantially raised the rate of premium pricing for innovativeness and usefulness to ensure appropriate evaluation of innovative pharmaceuticals. MHLW continues to use the full range of premium levels available for scientific evaluation of innovation. MHLW also will continue to provide to *Chuikyo* aggregated data on the results of applied premiums, including the number and type of premium.
- (4) Foreign Price Adjustment Rule for Pharmaceuticals: MHLW continues to take appropriate measures to ensure that innovative pharmaceuticals continue to be available in Japan to contribute to high-quality healthcare for Japanese patients. MHLW will continue to provide meaningful opportunities for industry, including U.S. industry, to consult on issues related to the Foreign Price Adjustment rule for pharmaceuticals.

b. *Medical Devices:*

- (1) Foreign Average Price (FAP) Rule for Devices: MHLW continues to take appropriate measures to ensure that advanced medical technologies continue to be available in Japan to contribute to high-quality healthcare for Japanese patients. According to the rule, which is set by *Chuikyo*, MHLW should use available prices of four countries, including the U.S., the U.K., Germany, and France in the medical device pricing revision process. MHLW will examine the methods used to collect information about appropriate pricing as well as the range of data used for the collection, in consultation with industry, including U.S. industry. While considering *Chuikyo's* concern over price differences between domestic and foreign markets, MHLW will call on industry to provide information on the costs specific to the Japanese market and consider the results of a U.S. industry study on the cost of doing business in Japan. The Government of the United States notes its view that the most appropriate comparator

is the U.S. list price. As MHLW prepares for the next biennial price revisions, it will review elements of pricing rules, including the FAP rule. MHLW will continue to provide meaningful opportunities for industry, including U.S. industry, to consult on issues related to the FAP rule and the scope of future data collection regarding medical devices.

- (2) C1 and C2 Pricing: MHLW will continue to provide pre-submission consultations for C1 and C2 applications to industry, including U.S. industry, and give necessary advice.
- (3) Clear Criteria on C1 Eligibility and Premiums: To further clarify the types of products eligible for C1 pricing, MHLW will describe to industry in FY2005 why certain products have been awarded or denied a C1 designation in the past. MHLW continues to provide companies, including U.S. companies, with opportunities for consultation regarding the application of the criteria for the C1 and C2 categories.

2. Visions:

- a. MHLW published the “Vision” policy papers for the pharmaceutical and medical device industries in August 2002 and March 2003, respectively. The Headquarters for the Promotion of Policies on the Pharmaceutical and Medical Device Industries of MHLW will make efforts to accelerate implementation of the “Visions” Action Plans in FY2005. Making efforts to accelerate implementation will foster innovation by providing market return incentives and will speed the introduction in Japan of safe and advanced drugs and medical devices. On April 28, 2005, MHLW issued a progress report on its implementation of the pharmaceutical Vision. Areas where progress was made in FY2004 included the environment of clinical trials and drug pricing.
  - (1) *Environment of Clinical Trials:* The number of people completing the Clinical Research Coordinator training course increased from 3,200 in FY2003 to 3,900 in FY2004. The number of medical institutions belonging to the “Large-Scale Clinical Trial Network” increased from 556 in FY2003 to 991 in FY2004. In FY2004, MHLW received three clinical trial notifications (“Japanese IND”) for Investigator-Initiated Clinical Trials.
  - (2) *Drug Pricing:* Through a study group called “Meeting to study the drug pricing system and drug benefits,” MHLW gathered information and exchanged opinions with industry regarding drug pricing and drug benefits over the medium to long term.

- b. On June 1, 2005, MHLW held a “Hearing on the Implementation of the Pharmaceutical Industry Vision Action Plan.” On June 10, 2005, MHLW held a “Hearing on the Implementation of the Medical Device Industry Vision Action Plan.” During those hearings, various industry representatives, including from U.S. industry, provided valuable input, which MHLW will seriously consider as it proceeds with the Visions.
3. Transparency: MHLW will continue to ensure the transparency of the reimbursement price-setting process. MHLW will continue to provide industry, including U.S. industry, with meaningful opportunities to provide input and with access to consultations prior to changes in pricing rules and when assessing their impact. Such consultations will occur in FY2005 while the Government of Japan prepares for biennial pricing revisions and considers changes in the reimbursement pricing system. MHLW will amend the format of the first meeting on product applications held by DPO on a trial basis starting in FY2005. In instances where DPO admits supplemental information would be beneficial to the decision-making process regarding the application of premiums, MHLW and DPO will allow applicants to make a presentation on their products’ effectiveness and usefulness in the first several minutes of the meeting.
4. Diagnostics: MHLW recognizes the value of diagnostics (e.g., in-vitro diagnostics (IVDs) and imaging devices) when determining diagnostic reimbursement pricing. For IVDs, MHLW continues a system to evaluate the clinical value of in-hospital tests and reflects this added value in reimbursement. MHLW will continue to include representatives of the imaging and in-vitro diagnostics industries in regular meetings with the medical device industry to exchange views regarding the reimbursement of diagnostics. MHLW has attended as an observer the IVD workshop that was established by the American Chamber of Commerce in Japan in April 2004. Workshop participants include academics and the Japan Association of Clinical Reagent Industries. In the workshop, participants have discussed various issues related to IVDs, including medical treatment fees, in-hospital testing, preventive medical diagnoses, and evaluation of data. MHLW will continue to ensure transparency for the diagnostics industry (e.g., in-vitro diagnostics and imaging devices) regarding the pricing process.
5. Biologics and Blood Products:
  - a. *Biologics*: MHLW recognizes the differences of development, manufacturing, and safety between biologics and chemical-based pharmaceuticals.
  - b. *Blood Products*: In FY2005, MHLW will continue to consult with the blood products industry regarding reimbursement pricing matters related to blood products.



6. Diagnosis Procedure Combination: MHLW will continue to study the impact of the Diagnosis Procedure Combination (DPC) system on various aspects of healthcare, including the average length of stay and treatment outcomes. MHLW will continue to provide industry, including U.S. industry, with information and meaningful opportunities to provide input and with access to consultations, upon request by industry, regarding the introduction or major revision of the DPC system. MHLW recognizes the importance of innovative products regarding the DPC system.
7. Data Exclusivity: As part of the “Intellectual Property Strategic Program” implemented by the Intellectual Property Strategy Headquarters (IPSH), the Government of Japan is considering extending the protection period for pharmaceutical test data from six years to eight years. MHLW will continue to study the issue of pharmaceutical test data with a view to enhancing incentives to develop new pharmaceuticals.

## **B. Medical Device and Pharmaceutical Regulatory Reform and Related Issues**

1. Introduction: In FY2005, MHLW will strive to speed the introduction of safe, effective, and innovative medical devices and pharmaceuticals and to provide Japanese patients with access to the best possible healthcare. The establishment of the Pharmaceuticals and Medical Devices Agency (PMDA) on April 1, 2004, and the implementation of major changes in the Pharmaceutical Affairs Law (PAL) on April 1, 2005, is expected to enhance the introduction of safe, effective, and innovative medical devices and pharmaceuticals in view of the Visions’ goals.
2. Performance Goals:
  - a. While endeavoring to achieve expeditious review and approval of pharmaceuticals and medical devices, MHLW will ensure that PMDA meets the annual performance goals for pharmaceuticals and medical devices described in the Third Report to the Leaders. The performance goals apply to applications submitted after the establishment of PMDA. MHLW and PMDA also recognize the importance of complying with the midterm (2009) goals.
  - b. MHLW recognizes the existence of the substantial backlog of medical device applications pending at the time of PMDA’s establishment and will strongly encourage PMDA to work as quickly as possible to eliminate the backlog. At the same time, MHLW will ensure that PMDA will process new applications within the timelines designated in PMDA’s performance goals.
  - c. MHLW recognizes the need to facilitate the drug consultation process. Per a notification on April 26, 2005, PMDA introduced a new reservation

system for consultations. If there are more requests for consultations than available time allotments, consultation appointments will be prioritized based on the importance of each pharmaceutical, according to criteria such as the current development stage of the drug and type of application. This system, which has been implemented since October 1, 2005, features a realignment in PMDA's consultation process structure and will optimize PMDA's consultation resources. PMDA will continue to consult with industry as it implements this system.

- d. For "me-too" medical devices as defined under the old PAL, MHLW will ensure that PMDA completes reviews in a manner equivalent to the one used under the old PAL, i.e., within four months. This will continue as a transitional measure until March 31, 2008, when the revised PAL has been fully implemented.
- e. The standard processing period for IVDs remains six months, as specified in the U.S.-Japan Report of 1986 on Medical Equipment and Pharmaceuticals under the Market-Oriented, Sector-Selective (MOSS) Discussions.
- f. MHLW will ensure that PMDA achieves the midterm goals of medical device reviews and will encourage PMDA to eventually exceed these goals.
- g. PMDA published its first annual report, which included information on its performance, on June 22, 2005.

3. Performance Metrics:

- a. The value of evaluating performance with appropriate measurements is recognized. The Governments of Japan and the United States welcome the constructive discussions that are taking place between PMDA and industry regarding the usefulness of performance metrics, and look forward to the successful conclusion of those discussions.
- b. The Government of the United States noted the importance of using several types of metrics to facilitate PMDA's performance and industry's business planning processes. For drugs, these metrics include the time from consultation request to meeting, from application to interview meeting, and from interview meeting to hearing; the annual number of standard NDAs, priority NDAs, and orphan drugs approved, submitted, and under evaluation; approval time for major variations and the number of variations approved, submitted, and under evaluation; and the number of Good Manufacturing Practice inspections conducted after the final evaluation report. For medical devices, these metrics include the number of applications (total and approved), number of cycles per review of

application documents, time spent on each step of evaluation, and time spent by reviewer.

4. Transparency:

- a. *Meeting with Industry:* In FY2005, MHLW and PMDA will continue to provide meaningful opportunities to exchange views with industry, including U.S. industry, regarding regulation of medical devices and pharmaceuticals. In the process of review-related activities, MHLW will ensure that PMDA ensures transparency by providing manufacturers with meaningful opportunities to be involved in the process.
- b. *Application Status:* In September 2004, PMDA established a mechanism to explain the communication process regarding the prospects, progress, and other matters related to reviews. In an important step to improve the transparency of the approval process, PMDA issued in September 2004 notifications announcing that a company that has applied for a new pharmaceutical or a new or improved medical device may request a meeting with PMDA to discuss the status of the agency's review of the product, including the expectation of the product's approval and the timing of several intermediate steps in the review process.
- c. *Memos:* For medical device clinical trial consultations, PMDA and an applicant create an official meeting memo. PMDA will continue to ensure that memos on consultations on clinical trials are provided to applicants and are based on mutual confirmation by PMDA and the applicants. For medical device simple consultations (*kani sodan*), PMDA, at an applicant's request, reviews meeting memos created by the applicant. MHLW will ensure that PMDA continues to be flexible on time limits to fulfill the purpose of the meetings.
- d. *Outside Advisors:* In striving to provide Japan with safe and effective medical devices and pharmaceuticals, MHLW and PMDA seek advice from experts in these sectors. PMDA publishes on its website a list of these experts. MHLW and PMDA will utilize external experts with appropriate knowledge of the relevant medical device or pharmaceutical. MHLW will avoid selecting experts with conflicts of interest as outside advisors.

5. Audits/Inspections: PMDA began auditing foreign manufacturing facilities from April 1, 2005, in connection with the enforcement of the revised PAL that stipulates new requirements for foreign manufacturing facilities. MHLW recognizes that pre-approval GMP/QMS audits based upon proper applications will generally be conducted in parallel with the product review and completed within the overall review period. MHLW and PMDA recognize that overseas pre-approval GMP/QMS audits, unless any substantial deficiencies have been

observed, will not unreasonably delay the review process for approvals of new products. MHLW and PMDA will continue to discuss with industry the practical application of paper inspections. With regard to the cooperation of the U.S. Food and Drug Administration (FDA) with PMDA to facilitate its GMP/QMS auditing of foreign manufacturing facilities, MHLW will continue to discuss this with the Government of the United States. PMDA will seek to exchange views on GMP/QMS auditing with industry in the same manner as FDA with domestic and foreign industry, including Japanese industry. On April 1, 2005, PMDA began conducting quality system audits for high-risk (Class 3 or 4) medical devices, and the 11 third-party recognized bodies in Japan, which were registered as of April 1, 2005, began conducting inspections for Class 2 devices in domestic and foreign plants. Class 2 products without recognized standards are subject to PMDA or prefectural government inspections.

6. Guidance for Medical Devices: When preparing new guidance concerning the standards, criteria, review procedures, and other matters related to medical devices, MHLW will ensure that opportunities for the public to comment continue to be provided. In FY2004, MHLW examined opportunities to increase the use of published guidance made by MHLW regarding reviews of medical devices. In FY2005, MHLW will issue more published guidance by MHLW regarding the premarketing and review phases for devices.
7. Staffing and Expertise: MHLW will ensure PMDA increases its resources and expertise, including recruiting qualified staff, to facilitate product reviews and safety. As of April 1, 2005, PMDA had 291 staff members. MHLW will ensure PMDA reaches its goal of 346 employees by March 31, 2009. PMDA will use one team for the clinical trial consultations and reviews of the same product. MHLW will ensure that PMDA provides reviewers with continuing education and that staff rotations enhance therapeutic expertise. In FY2004, PMDA provided several training opportunities to its staff as appropriate. MHLW will ensure that PMDA's reviewers enhance their expertise through continuing education and other opportunities.
8. Streamlining Medical Device Reviews: PMDA has taken steps to streamline reviews of medical devices. In 2005, MHLW confirmed that partial changes in manufacturing processes or product designs are suitable for notification rather than approval if such changes do not affect safety or efficacy. On April 1, 2005, the STED (Summary Technical Documentation) became part of Japan's regulatory system. MHLW and PMDA will reduce the documentation for medical devices that have approval standards.
9. Fast Track and Priority Review: On February 27, 2004, MHLW issued Notification 0227016 that described the fast track and priority review processes. PMDA is making efforts to facilitate the priority and regular review processes.

10. Combination Therapies and Products: On March 25, 2005, Japan's Cabinet approved a revised Three-Year Plan for Regulatory Reform and Private Sector Participation, which calls for the relaxation of approval requirements for combination drugs in FY2005. On March 30, MHLW issued a notification to clarify the approval criteria for combination drugs in the application for approval of pharmaceuticals. It has included the following additional criteria: (i) drugs that apparently enhance patients' convenience, and (ii) drugs that have scientific justification for being combined.
11. Appeals: In March 2005, PMDA issued a notification to clarify how to deal with appeals from industry related to its services including reviews and safety activities. The notification specified measures PMDA will take in response to complaints about its review and safety activities including requiring directors to respond to complaints within 15 working days to the greatest extent possible. Applicants can make science-based appeals regarding PMDA's decisions at a meeting with PMDA and outside scientific experts. PMDA incorporated industry's views in structuring its appeals mechanism.
12. Safety: MHLW will ensure that PMDA increases its efforts to exchange views with the relevant company when reviewing adverse event reports, and particularly when an adverse event may require a response.
  - a. For medical devices, MHLW will align the postmarketing safety requirements and practices with Global Harmonization Task Force (GHTF) guidance documents as appropriate. As of April 1, 2005, MHLW allows periodic reporting for inconsequential events.
  - b. For drugs, PMDA is currently developing a safety database and a data mining analysis, and will make public its progress at the appropriate time. MHLW will ensure that PMDA develops this data mining analysis in a transparent manner, and provides industry, including U.S. industry, with opportunities to give input as it proceeds.
13. Standards for Medical Devices: In FY2005, MHLW will adopt for medical devices international standards and guidance documents developed by organizations such as the GHTF, ISO, and IEC without substantive modification as much as possible. Where modifications are deemed necessary, MHLW always uses the public comment procedure. MHLW will ensure that opportunities for the public, including U.S. industry, to provide input in various ways, including through public comment procedures, continue to be provided when developing new standards for medical devices. MHLW developed 363 recognized standards for 765 Class 2 medical devices as of April 1, 2005. MHLW will continue to develop recognized standards for Class 2 devices.
14. GCPs for Medical Devices: In FY2005, MHLW will accept clinical data obtained outside of Japan for medical devices as long as the applicant proposing a device

shows that the data comply with Good Clinical Practices that are regarded as substantially equivalent to Japan's GCP standards.

15. Market Authorization License System: On April 1, 2005, as part of the postmarketing safety changes resulting from reform of the Pharmaceutical Affairs Law, MHLW replaced its In-Country Caretaker system with a Marketing Authorization License system. MHLW recognizes the impact of the transition to a new system on the ability of foreign manufacturers to remain in the Japanese market and supply their products and has already taken measures including establishing a transition period. MHLW will continue to exchange views with industry, including U.S. industry, regarding the transition to the new system.

### C. **Blood Products**

1. Industry Input: MHLW will work actively with interested parties, including industry, to ensure that doctors and patients receive accurate information about the risks and benefits of various therapies, including those involving blood products. In FY2004-2005, MHLW worked with all interested parties to hold meetings to discuss issues related to securing a stable supply of blood products including patient care, declining demand, and other topics. For example, MHLW invited the representatives of relevant industries to attend the Subcommittee on Demand and Supply of Blood Products in March 2005. In FY2005, MHLW will continue working with the interested parties to address these concerns. MHLW will continue to provide opportunities to interested parties, including U.S. industry, to express their views on these issues.
2. Transparency: MHLW will continue to ensure that implementation of the Supply and Demand Plan does not discriminate against foreign products, is transparent, and is fully consistent with Japan's international trade obligations.

### D. **Nutritional Supplements Liberalization**

1. Educational and Informational Statements: In FY2005, MHLW expanded the scope of educational and informational statements on labels and in advertising for Foods for Specified Health Uses (FOSHU). Based on the Codex Alimentarius, MHLW intends to consider revising the Japanese system for foods with health claims including other foods.
2. Import Duties: The Government of Japan will address the issue of tariff levels, including on nutritional supplements containing the same ingredients as pharmaceuticals, in WTO negotiations comprehensively.
3. Codex: MHLW will harmonize its regulations with the international guidelines and standards established at Codex. Japan will take a more active role in developing these guidelines and standards at this international forum.

4. Potency Limits: MHLW will base the revision of the maximum and minimum values set in the Food with Nutrient Function claims on international standards.

## **V. FINANCIAL SERVICES**

### **A. Furthering the Promotion of Regulatory Reform**

1. Japan continues to make progress in opening and liberalizing its financial services market. This process started with the 1995 “Measures by the Government of Japan and the Government of the United States regarding Financial Services” and accelerated under Japan’s “Big Bang” financial liberalization initiative launched in 1996, which committed Japan to fundamental deregulation of the financial sector. Under its two-year “Program for Financial Revival,” the Financial Services Agency focused on ensuring financial system stability, achieving its goal of reducing major banks’ non-performing loans ratio to about half by the end of March 2005.
2. In December 2004, the FSA unveiled its new two-year “Program for Further Financial Reform” (“Program”), signaling a shift in its focus from ensuring financial system stability to promoting financial system vitality by enhancing user protection and convenience, while boosting the ability of financial institutions to offer a wider range of services quickly. Under the new Program, the FSA has set forth an aggressive, wide-reaching work schedule. Its aim is to point out a road map for financial reform to ensure Japan’s future as a highly advanced “financial services nation.”
3. The Program work schedule provides for reforms in a broad range of key areas including distribution, pricing, advertising, market conduct, user protection, corporate governance, disclosure, and risk management. These reforms may result in sweeping changes to numerous laws, regulations, and guidelines. Given the substantial impact these reforms could have on the global financial system and to U.S. financial service suppliers operating in Japan and Japanese financial service suppliers operating in the United States, the Governments of Japan and the United States will discuss implementation of the Program and will discuss as necessary other issues regarding the market for financial services during the bilateral financial services discussions under the Financial Dialogue of the Economic Partnership for Growth or other occasions.
4. In launching the Program, Japan recognizes the need to create a concrete program for financial reform as part of its overall structural reforms essential to fostering sustainable economic growth and to responding to an aging population, falling birthrate, and continued economic globalization.
5. The United States supports generally the principles espoused under the Program. Both governments share the goal of fostering open, prudentially sound, vital, and internationally respected financial systems in which user satisfaction is a core

value, and which are led not by the public sector, but by private sector initiative. Key to achieving these goals are continuing efforts to develop a framework to improve the transparency and predictability of financial administration consistent with adherence to the principle of equal treatment between Japanese and non-Japanese financial institutions.

6. The Governments of Japan and the United States recognize the value of bilateral cooperation in such forums as the bilateral financial services discussions under the Financial Dialogue of the Economic Partnership for Growth as essential to further strengthening partnerships between U.S. and Japanese financial regulatory authorities.

## B. **Specific Measures**

1. Trust Bank License: The Government of Japan is studying revision of such laws as the Trust Business Law and the Concurrent Operation Law in the context of its plan for future amendment of the Trust Law. In the process of the study, the Government of Japan will consider equitable treatment of foreign bank branches as one of the discussion points.
2. Defined Contribution Pensions: The Government of Japan raised contribution limits on private DC pension plans for employees for whom the companies do not provide any company pensions in October 2004. The Government of Japan also eased the requirements for early withdrawal in October 2005 because the withdrawal fee can reduce or extinguish the asset if it is small. Ministry of Health, Labour and Welfare is promoting investment education in a continuous and programmed manner to further promote DC pensions, while studying ways to make DC pensions a more attractive retirement plan alternative by further increasing contribution limits and other reforms.

C. **Transparency -- No Action Letters**: In an effort to enhance the transparency of financial administration, the FSA continues to make progress in promoting more active use of its No-Action Letter (NAL) system. Moreover, the FSA is studying measures to further enhance its NAL system and develop other means of expanding the body of written interpretations of Japanese financial law and regulations as a key element of its Program for Further Financial Reform. Steps taken to date and measures now in progress include:

1. The number of NAL published by the FSA is increasing. The FSA has issued 11 No-Action Letters since April 2004, compared to 6 issued in the previous 12 months and 4 during the first 21 months after the NAL system was introduced in July 2001.
2. Under the Program for Further Financial Reform, the FSA has taken or will take the following steps to encourage more active use of its NAL system and to enhance the system itself. Specifically, the FSA has:



- a. Promoted awareness of the NAL system by publishing in February 2005 “Detail of the No-Action Letter System,” which is an English-language version (Provisional Translation) of the bylaws of the NAL system;
  - b. Distributed in June 2005 a detailed questionnaire survey to the general public (including regulated firms) with regard to the NAL system and suggestions for improvement of the implementation of the FSA’s application of the NAL system and its laws and bylaws; and
  - c. Improved the NAL system, in October 2005, by amending the system’s bylaws to reflect the results of the aforementioned survey. The FSA will publicize these amendments through various channels.
3. In addition to the NAL system, the FSA has also begun studying measures to increase the body of written interpretation of Japan’s financial laws and regulations, including the following measures:
- a. Discussing establishment a “List of Reference Cases,” by this Fall, that will provide examples of the FSA’s interpretation of laws and regulations; and
  - b. Reviewing the guidelines for supervision with regard to “responses in case of receiving general inquiries regarding interpretation of laws and regulations.”

## **VI. COMPETITION POLICY**

### **A. Strengthening the Effectiveness of Antimonopoly Enforcement**

1. Amendment of the Antimonopoly Act: On October 15, 2004, the Government of Japan submitted the Bill to amend the Act Concerning Prohibition of Private Monopolization and Maintenance of Fair Trade (the Antimonopoly Act or AMA), which was enacted by the Diet on April 20, 2005. This legislation, the first major amendment to the AMA in 28 years, represents Japan’s decision to establish a competition policy that fits the social and economic environment of the 21st Century, based on market mechanisms and the principle of self-determination. The Fair Trade Commission of Japan (JFTC) held the Study Group on the AMA since 2002 to review the AMA, and the Study Group issued its report in October 2003. Based on the Study Group report, as well as consideration of the views of a variety of stakeholders including business associations, bar associations and consumer associations, JFTC drafted the Bill to amend the AMA. The amendments will come into effect on January 4, 2006 and are expected to significantly strengthen JFTC’s capabilities to enforce the AMA and to eliminate and deter anticompetitive activities, in particular hard-core cartels and bid rigging activities. The most significant aspects of the bill provide for:

- a. Strengthening the surcharge system by:
- (1) Increasing the surcharge rate from 6 percent to 10 percent for large manufacturers and service suppliers (from 3 percent to 4 percent for small and medium-sized enterprises (SMEs)); from 2 percent to 3 percent for large-sized retailers (from 1 percent to 1.2 percent for SME retailers); and from 1 percent to 2 percent for large-sized wholesalers (SME wholesalers stay at 1 percent);
  - (2) Imposing a surcharge rate of 150 percent of the normal surcharge on enterprises that are repeat AMA offenders within 10 years from the previous surcharge order;
  - (3) Expanding and clarifying the scope of conduct subject to surcharge to include (a) unreasonable restraints of trade (cartels) substantially restraining output, market share or customers, (b) illegal buying cartels and (c) certain private monopolization that is implemented in a manner equivalent to a cartel subject to surcharges; and
  - (4) Providing that surcharge orders are effective immediately upon a JFTC determination in a case and are not extinguished if the respondent chooses to seek review in a hearing procedure. If the respondent fails to pay the surcharge by the due date and the surcharge is sustained by a decision after hearing procedures, the respondent must pay interest at the rate provided for by Cabinet Order. If the surcharge payment order is discharged by a decision after the respondent has paid the surcharge, JFTC will pay back to the respondent the surcharge, adding interest as provided for by Cabinet Order.
- b. Introducing a leniency program that:
- (1) Eliminates the full amount of the surcharge to the first company that, prior to the initiation of a JFTC investigation, discloses to JFTC the existence of a cartel or bid rigging conspiracy and meets other statutory conditions. Moreover, JFTC will further strengthen the effectiveness of the leniency program by implementing a policy that it will not file a criminal accusation against that company or any of its employees. The policy was announced in “The Fair Trade Commission's Policy on Criminal Accusation and Compulsory Investigation of Criminal Cases Regarding Antimonopoly Violation” on October 6, 2005; and
  - (2) Reduces the surcharge amount by 50 percent and 30 percent for the second and third firms, respectively, that qualify for the leniency

program before initiation of a JFTC investigation, or by 30 percent for firms that qualify for the leniency program after JFTC has initiated an investigation, consistent with the condition that no more than three enterprises in total may enter the leniency program.

- c. Strengthening the effectiveness of JFTC's investigations to uncover and act against, *inter alia*, hard-core cartels and bid rigging conspiracies by:
  - (1) Providing JFTC designated staff members with the power to obtain compulsory search warrants in cases where criminal accusations are being pursued;
  - (2) Increasing criminal penalties against corporate officials and corporations that interfere with JFTC investigations from the previous maximum of a 200,000 yen fine and imprisonment of up to six months, to a fine of up to 3 million yen and imprisonment for up to one year;
  - (3) Strengthening penalties against corporations that fail to comply with JFTC cease and desist orders from the previous maximum fine of 3 million yen to a maximum fine of 300 million yen; and
  - (4) Extending the statute of limitations for JFTC to issue cease and desist orders from one year after the unlawful conduct has been terminated to three years.
  
- d. With the goal of increasing the fairness of JFTC procedures:
  - (1) The proposed recipient of a cease and desist order or a surcharge payment order will be given the opportunity to rebut the allegations against it, including by submitting evidence and making arguments in its defense, prior to the issuance of such orders by JFTC (eliminating the current recommendation system that provides for issuance of a decision only if the respondent consents, or after an extended hearing procedure.)
  - (2) In adopting its rules and procedures, JFTC will take into consideration the necessity of ensuring due process for respondents, including by ensuring that respondents have an adequate opportunity to respond to allegations and to state their defense.
  
- e. In order to ensure the effective implementation of the new AMA amendments:

- (1) JFTC prepared implementing regulations, which were published for public comment and finalized on October 6, 2005; and
- (2) JFTC will increase its public outreach activities to enhance public awareness of the new amendments, including by holding seminars for the public and business community.

2. Criminal Enforcement of the AMA:

- a. In May and June 2005, JFTC filed criminal accusations against a total of 26 companies and eight individuals for their participation in a conspiracy to rig bids on steel bridge construction projects ordered by the Ministry of Land, Infrastructure and Transport (MLIT), the first criminal accusations by JFTC since July 2003. And in June and August 2005, JFTC filed criminal accusations against a total of six companies and four individuals for their participation in a conspiracy to rig bids on steel bridge construction projects ordered by the Japan Highway Public Corporation (JH).
- b. JFTC will vigorously use its new criminal investigation powers against vicious and serious violative conduct, particularly hard-core cartel and bid rigging cases.

3. AMA Exemptions: With the aim of ensuring that AMA exemptions are as limited as possible, JFTC continues to review remaining AMA exemptions, to determine whether any can be further narrowed or eliminated, including the exemption for resale price maintenance agreements involving copyrighted works. In that regard, a council composed of JFTC officials, industry representatives, academic experts and consumer representatives meets periodically to review whether the exemption for resale price maintenance for copyrighted works is applied flexibly so as to lead to improvement of consumer interest. The last meeting of the council took place in June 2005.

4. JFTC Resources:

- a. For JFY2005, JFTC received a budget increase of 4 percent to 8.131 billion yen and a net increase of 34 staff, bringing its total staff levels to 706 as of March 31, 2006.
- b. In order to strengthen its analysis of the economic and legal implications of suspected anticompetitive conduct, JFTC is endeavoring to improve the analytical capabilities of its staff through recruitment efforts and training of existing staff. As of October 2005, eight JFTC staff have post-graduate degrees in economics, including one associate professor, and 10 are qualified as lawyers, one of whom had been a judge before joining JFTC and now is working as a hearing examiner. JFTC will increase the number

of staff with post-graduate economics training, as well as those with advanced legal training. Five JFTC staff are currently receiving advanced economic or legal training in graduate schools.

5. AMA Compliance:

- a. Since the amended AMA strengthens the enforcement capabilities of JFTC, including through introduction of a leniency program, it is becoming more and more important for companies to promote their own compliance with the AMA. JFTC will, through increased public relations activities and other means, encourage companies to adopt or enhance their AMA compliance programs.
- b. JFTC will, in order to assist companies in complying with the AMA, issue guidelines when necessary to clarify conduct that violates the AMA. For example, on June 29, 2005, JFTC issued Guidelines on Standardization and Patent Pool Arrangements. Currently, JFTC is disseminating the Guidelines by holding briefings.

**B. Increasing Procedural Fairness of JFTC Enforcement Activities**

1. Hearing Procedures: For the purpose of increasing procedural fairness in JFTC hearing procedures, the JFY2005 budget provides for the addition of two hearing examiners to JFTC staff that are qualified attorneys, with the result that three out of the seven JFTC hearing examiners will be qualified attorneys or judges.
2. Warnings: JFTC will introduce a system by early January 2006 that will allow proposed recipients of warnings against suspected AMA infringement (*keikoku*) by JFTC to submit evidence and arguments in their defense prior to the issuance of such warnings.
3. Cautions: Only when JFTC considers it preferable from the viewpoint of competition policy will it make cautions (*chui*) public, with the consent of the recipients.
4. Review of JFTC Procedures: A study group under the Cabinet Office is undertaking a review of the AMA from the standpoints of ensuring procedural fairness in administrative hearing procedures and other aspects of the AMA enforcement system, to be completed around June 2007.

**C. Addressing Bid Rigging Effectively**

1. Prevention of Bid Rigging, including Government-led Bid Rigging:
  - a. In response to the criminal accusation filed by JFTC on May 23, 2005 against eight companies for bid rigging on steel bridge construction

projects ordered by MLIT and the subsequent arrest of officials from three additional companies, MLIT suspended for eight months a total of 11 companies from bidding on any construction project tenders by the three MLIT regional bureaus whose bids were allegedly rigged and for five months from bidding on the tenders of MLIT's other regional bureaus. At that time, eight months was the longest suspension from bidding ever ordered by MLIT as a result of a violation of the AMA. Following the subsequent series of arrests and prosecutions related to the steel bridge case, MLIT has extended the suspension on the offending companies. As a result, 26 companies including those suspended additionally have been suspended as of September, 2005.

- b. In order to strengthen measures to prevent bid-rigging on government-ordered construction projects, MLIT has established a 12-member committee chaired by the Vice-Minister of Land, Infrastructure and Transport to examine why current measures are failing to prevent the occurrence of large-scale bid rigging, such as the bid rigging conspiracy on construction of steel bridges that was the subject of a criminal accusation in May 2005. MLIT has also established a five-member advisory group made up of scholars and lawyers to provide outside expert opinions to contribute to the discussion of the committee. The committee compiled the results of its survey about bidding procedures and contract awards relating to steel bridge construction projects ordered by MLIT. Based on the results of the survey, the committee formulated countermeasures to prevent recurrence of bid rigging that were issued on July 29, 2005. Those MLIT countermeasures include expanding the coverage of the open and competitive bidding procedure and the overall greatest value methodology as well as strengthening penalties for serious bid rigging violations by clarifying the maximum 24 month-period of suspension from bidding and increasing the pre-established damages in construction services contracts from 10 percent to 15 percent of the contract price.
- c. When JFTC finds that officials of public procuring entities have been involved in bid rigging:
  - (1) JFTC will notify the head of the procuring entity of the facts surrounding the matter, including, where it has obtained sufficient evidence, the names of the public officials involved in the bid rigging; and
  - (2) JFTC may demand under the Act Concerning Elimination and Prevention of Involvement in Bid Rigging, that such head official take necessary measures to improve the administration of bidding and contracts to eliminate such involvement by public officials in the future. In this regard, in September 2005, since JFTC

recognized the involvement by JH in the bid rigging, JFTC demanded that the President of JH take necessary measures to prevent the recurrence of bid rigging.

- d. In light of the AMA amendments establishing the JFTC leniency program, MLIT will initiate an examination within JFY2005 of whether to adopt an administrative leniency program that would exempt from certain administrative sanctions a company that comes forward to report to JFTC its participation in a bid rigging conspiracy.
- e. As part of the Three-Year Program for the Promotion of Regulatory, adopted by the Cabinet on March 25, 2005, the Government of Japan decided to improve the operation of the government procurement system by phasing in measures that will ensure more competition in the bidding process with the goal of lowering the cost and increasing the quality of services received by the government.

2. Bid Rigging at the Local Government Level:

- a. The Government of Japan recognizes the importance for local governments to address bid rigging strictly. The Law for Promoting Proper Tendering and Contracting for Public Works (Proper Tendering Law) provides a number of measures to prevent bid rigging both at the central and local government level, including an obligation for local governments to notify JFTC of any suspicious facts relating to possible bid rigging on orders for public construction works they have placed.
- b. The Ministry of Internal Affairs and Communications (MIC) has been and will continue to take appropriate steps to eliminate bid rigging at the local government level.
  - (1) In this regard, MIC, together with MLIT, issued a notice to all local governments on December 28, 2004 requesting them to take thorough measures to eradicate bid rigging, including by educating their officials on how to prevent bid rigging and establishing mechanisms to collect and publicize information about bid rigging in order to facilitate transmission of information about suspected bid rigging to JFTC.
  - (2) MIC and MLIT have been and will continue to conduct surveys on the measures taken by local governments to comply with the Proper Tendering Law and to publish the results of their surveys on their websites, and will continue to issue notices related to the eradication of bid rigging as necessary.

- (3) MIC is also making efforts to encourage local governments to revise their bidding processes and to introduce new bidding systems, such as the use of Internet-based bidding, that will be better at preventing bid rigging at the local level.

3. Transparency in Administrative Sanctions against Bid Rigging:

- a. MLIT will make public on its website a list of all companies subject to suspension of designation, including those suspended because of bid rigging activities, the period and scope of the suspension, and the reasons for the suspension. MLIT will also make public the amount each company found to have engaged in bid rigging pays to compensate MLIT for its damages from the bid rigging.
- b. MIC has encouraged and will continue to encourage local procuring entities to publicize the trade names of companies subject to suspension of designation, including those suspended due to committing bid rigging, the period and reasons of the suspension and other related matters.

**D. Promoting Competition Throughout the Economy**

1. Privatization in a Pro-Competitive Manner:

- a. Ministries and agencies in charge of the privatization of individual government-affiliated entities will cooperate and coordinate with the relevant ministries to ensure that privatization promotes, rather than impedes, competition in the relevant market.
- b. With respect to the privatization of Japan Post, the Government of Japan will ensure that the preparation and implementation of Japan Post privatization does not distort the competitive process in Japan. The privatized companies will be subject to the AMA, including during the process of privatization.
- c. JFTC will take appropriate actions on privatization efforts from the viewpoint of competition policy, including with regard to privatization of Japan Post. JFTC monitors business activities, including those of government-owned entities in the process of privatization, and will take stringent action against conduct that infringes the AMA.

2. Promoting Competition in Regulatory Reform:

- a. JFTC will continue to make efforts for the creation of a competitive environment in industries subject to regulation, from the viewpoint of promoting competition among business. For this purpose, JFTC will make policy recommendations -- based on actual conditions of trade and, where



applicable, findings of AMA violations -- in order to improve regulatory systems that have anticompetitive effects on business activities.

- b. JFTC will issue or revise guidelines, as necessary, to promote conduct in public utility and other sectors undergoing regulatory reform that is procompetitive and consistent with the AMA. For example, over the past year, JFTC has issued or revised the following guidelines:
  - (1) Guidelines concerning the Promotion of Competition Policy in the Telecommunications Business Field (revised June 2004);
  - (2) Guidelines concerning Appropriate Dealing in the Natural Gas Sector (revised August 2004);
  - (3) JFTC's Views on the Number Portability Systems of Mobile Phones based on the AMA (published November 2004); and
  - (4) Guidelines concerning Appropriate Electric Power Dealings (revised May 2005).

## **VII. 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. On March 11, 2005, the Government of Japan submitted a bill to the Diet to modify the Administrative Procedure Law containing the legislation of the PCP, which passed the Diet on June 22. Consistent with this objective, the amended Administrative Procedure Law 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. In cases where only the summary of the comments is made public by using the Internet, Ministries and Agencies are required to make available the complete text upon request.

2. MIC will continue to conduct and publish a comprehensive annual survey on the Ministries' and Agencies' implementation of the PCP, and will maintain close communications with relevant Ministries and Agencies in this regard.
3. The Government of Japan remains aware of the Government of the United States' continuing interest in the future developments of Japan's PCP, including the status of its implementation.

**B. Special Zones for Structural Reform:** 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 548. The Government of Japan is taking necessary steps to ensure that successful zones have the largest economic impact on the greater Japanese economy. To this end, the Government of Japan is:

1. Operating the entire application and regulatory exemption process for the Special Zones in a transparent manner;
2. Working to expand market-entry opportunities in the Special Zones;
3. Ensuring domestic and foreign companies alike have non-discriminatory access to operate in the zones;
4. Applying successful regulatory exemptions in the Special Zones on a national basis as expeditiously as possible;
5. Ensuring opportunities for U.S. and other foreign companies to submit proposals for regulatory exemptions for Special Zones and to make proposals to local municipalities to establish Special Zones; and
6. Responding as fully as possible to inquiries made by foreign companies for information on Special Zones.
7. Ensuring the Evaluation Committee for the Special Zones undertakes the following in determining which regulatory exemptions in the Special Zones should be applied nationwide.
  - a. Ensure transparent decision-making process through open meetings and publicly available information to determine nationwide regulatory exemptions; and

- b. Publication of the decisions and supporting information on evaluations after the decisions are made so that all interested parties can fully understand the evaluation process.
- C. **APEC Transparency Standard:** APEC leaders have agreed to a package of transparency standards for the range of trade and investment areas. The United States and Japan have worked closely to develop these standards. Accordingly, the United States and Japan will continue to work jointly to achieve full implementation of the APEC Transparency Standards in the domestic legal regimes of APEC member economies.
- D. **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.
- E. **Policyholders Protection Corporation:** An amendment to the Insurance Business Law which passed the Diet on April 22, 2005, includes the revision of the Life and Non-Life Insurance Policyholders Protection Corporation (PPC). Under the revised system, compensation rates for insurance policies of higher guaranteed interest rates will be reviewed, and the contribution percentages for the insurance industry and the Government of Japan will be restructured. The Financial Services Agency (FSA) announced, on October 12, 2005, draft amendments of Cabinet and Ministerial Ordinances necessary to introduce the new system and solicited public comments on them. The FSA will provide adequate opportunities upon request for interested parties to be informed of, comment on (including by soliciting public comments on draft ordinances or regulations, if any), and exchange views with relevant officials and advisors of the Government of Japan with respect to relevant laws and regulations regarding the Life and Non-Life PPCs.
- F. **Postal Financial Institutions:** On October 14, 2005, the Diet passed bills related to privatization of Japan Post. The measures related to the privatization of Japan Post are referred to under the section “Privatization: Privatization of Japan Post.” The following measures will be taken with respect to the existing postal financial institutions.
  - 1. The Ministry of Internal Affairs and Communications (MIC) will continue to provide opportunities for private life insurance and other financial companies, upon request, to exchange views with relevant officials on Kampo and Yucho inspection and taxation requirements.
  - 2. With regard to the formulation of proposals to seek from the Diet amendments to law related to Kampo products and distribution or origination by Japan Post of non-principal-guaranteed investment products, the MIC recognizes the importance of informing the general public of such formulation of proposals and will provide meaningful opportunities for private sector interested parties upon request to exchange views with relevant officials. Japan Post cannot originate any non-principal-guaranteed investment products, nor introduce new lending services

not offered at present, as the Japan Post Law does not include any provisions describing these products or services.

3. The Government of Japan has continued to regularly provide the Government of the United States with data related to the sales of a new Kampo product in January 2004. This information will continue to be provided upon request, and the Governments will continue to maintain communication on this subject.
4. The Government of Japan is aware of the strong concern of the Government of the United States that a level playing field should be established between postal financial institutions and their private sector competitors, whereby these institutions are subject to the same regulatory, legal, and tax requirements. The Government of Japan furthermore is aware that the Government of the United States has requested that no new or altered Kampo products or new lending or other related banking services to businesses or individuals or the origination of any new non-principal-guaranteed investment products should be introduced until such a level playing field is established. The Government of Japan confirms that Japan Post now has no plans to introduce any new or altered Kampo products or riders.

#### **G. Bank Sales of Insurance**

1. A report of the Financial Systems Council issued in March 2004 recommended full liberalization, in principle, of banks sales of insurance products to be undertaken in a phased manner within a specified period. Following the report, on July 8, 2005, the FSA amended the regulations based on public comments. The new regulations envisage the first stage of liberalization to begin by December 2005 with a view toward full liberalization after two years of monitoring. Consistent with the recommendations of the Financial Systems Council, the new regulations include a set of consumer protection rules.
2. The FSA will provide meaningful opportunities, upon request, for interested parties to be informed of, comment on, and exchange views with relevant officials and advisors of the Government of Japan with respect to the effectiveness of the consumer protection rules during the monitoring period as well as the implementation of the liberalization of bank sales of insurance.

#### **H. Insurance Cooperatives**

1. An amendment to the Insurance Business Law, which passed the Diet on April 22, 2005, includes several measures regarding “unregulated kyosai.” In principle, kyosai that are currently unregulated will be supervised by the FSA under the amended law. In addition, a new registration system will be applied to the insurers which only provide small-amount and short-term insurance products.

2. The FSA will solicit public comments in the process of establishing regulations to implement the new system. The FSA will also provide meaningful opportunities, upon request, for interested parties to be informed of, comment on, and exchange views with relevant officials and advisors of the Government of Japan with respect to relevant laws and regulations regarding “unregulated kyosai,” including with respect to the legislatively-mandated review of the new system.
3. 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.

I. **Government Practices Relating to Agriculture:** In 2004, the U.S.-Japan Regulatory Reform and Competition Initiative took up issues related to agriculture that examine the adoption of international regulatory standards in key areas of plant quarantine. Internationally adopted plant quarantine standards both increase transparency and reliance on science-based decision making - two essential components of trade in agriculture.

1. In December 2004, the Governments of Japan and the United States decided to hold a joint workshop with technical and policy experts to examine the adoption of two key standards established by the International Plant Protection Convention (IPPC): (1) official control for plant quarantine pests; and (2) pest risk analyses (PRAs). At the workshop, held in Tokyo April 26-28, 2005, the Governments of Japan and the United States made presentations and had a constructive exchange of views on the interpretation and application of IPPC standards related to official control and PRAs. Through valuable discussions conducted at the workshop, both Governments deepened their mutual understanding on plant quarantine systems. Specifically:
  - a. The Government of the United States provided an explanation of the concept and application of IPPC official control and PRA standards;
  - b. Both Governments discussed specific examples of official control and the development of PRAs conducted by each Government;
  - c. The Government of Japan also explained that:
    - (1) The Japanese pest forecast system (PFS) does not correspond to the IPPC standard on official control, since target pests of the PFS are not legally required to be officially controlled. Further, the Government of Japan highlighted that there are several cases where it has removed target pests from the import quarantine list as a result of conducting PRAs; and

- (2) It will continue to conduct import PRAs for quarantine pests, including target pests of the PFS in accordance with the relevant IPPC standards to determine if the pests should be subject to quarantine measures.
2. Furthermore, to enhance the understanding of PRA implementation in both countries, Japanese plant quarantine experts will visit the USDA/APHIS Center for Plant Health Science and Technology, Plant Epidemiology and Risk Analysis Laboratory in Raleigh, North Carolina, before the end of 2005 to gain greater understanding of the Government of the United States' procedures for conducting PRAs.

## VIII. 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 September 2005, the Government of Japan conducted necessary measures (amendment 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 41 times since its launch in July 2002. The summaries of the minutes of those meetings and discussion papers have been made public.

- B. Privatization of Japan Post:** On October 14, 2005, the Diet passed bills related to privatization of the postal services that are based on the Cabinet's September 2004 Basic Policy on the Privatization of Japan Post. According to the legislation, the purpose of the privatization of Japan Post is to enhance the autonomy, creativity and efficiency of management and to promote fair and free competition by privatizing and dividing Japan Post into separate stock corporations according to function and by taking measures to ensure equal footing with their competitors, while considering the impact on the local community and on the market, and thus stimulating the economy through greater freedom for funds investment and improving public benefits and convenience through the provision of a variety of high-quality services.

1. Postal Insurance and Postal Savings:
  - a. The laws on postal services privatization stipulate that the current Postal Savings Law and Postal Life Insurance Law should be revoked and the postal savings and postal life insurance functions of Japan Post should be transferred to the Postal Savings Bank and the Postal Insurance Company, respectively, in October 2007. From the beginning of the privatization transition period, the new financial companies will be supervised by the Financial Services Agency (FSA) under the Banking Law and the Insurance Business Law according to the same standards including the arms-length rule as those applied to other banks and insurance companies, and will be subject to the same tax obligations as well as accounting and disclosure requirements as other private sector stock companies including those when engaging in public capital market transactions. From October 2007, the Post Office Company, a network service supplier, will be subject to FSA supervision according to the standards applied to private companies when engaging in sales and distribution of financial service or insurance products. Also from October 2007, the Postal Savings Bank and Postal Insurance Company will be obliged to join the Deposit Insurance Corporation of Japan and the Life Insurance Policyholders Protection Corporation respectively on the same terms as other banks and life insurance companies, as special government guarantees on new deposits and insurance contracts will be abolished.
  - b. The laws also impose business restrictions on the Postal Savings Bank and Postal Insurance Company during the transitional period as special provisions to the Banking Law and the Insurance Business Law. The initial scope of business of the new financial companies will be same as that of Japan Post. Future expansion of business scope must go through a transparent and fair procedure whereby the Prime Minister (whose power is delegated to the Commissioner of the Financial Services Agency) and Minister of Internal Affairs and Communications, upon hearing an opinion from the Postal Services Privatization Committee (PSPC) (a third-party organization comprised of intellectuals), will decide on such expansions. Equivalent conditions of competition and management freedom shall be considered in evaluations of new product introductions when the ministers in charge make decisions on business expansions of the new companies. The introduction of new or altered insurance products by the Postal Insurance Company or new non-principal-guaranteed investment products or new lending services by the Postal Savings Bank will be reviewed through the process described above. The conditions described in 1.a, 1.c. and 1.d. will be considered, including by the PSPC, when new or altered product applications are submitted for review.
  - c. The laws 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 the 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. 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 FSA oversight and supervision. 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 PSPC prior to government approval (to take place before October 2007), taking into consideration competitive conditions of new financial companies with other private financial institutions.

- d. According to the laws, as of October 2007 the Postal Savings Bank and the Postal Insurance Company will be subject to the same legal and regulatory requirements applied to their private sector competitors, except for special provisions of the Postal Services Privatization Law that impose stricter business restrictions on the new financial companies during the transition period.

2. Express Delivery Services:

- a. The privatization laws provide that the Postal Service Company -- on the basis of being subject to the same regulations as those for other private companies and providing no scheme for the Postal Service Company to receive any special benefits beyond minimum necessary measures to secure universal services -- should be subject to the supervision of the Minister of Land Infrastructure and Transport under freight transportation laws and ordinances when providing postal services business and domestic and international logistics business, and should be subject to the supervision of the Minister of Internal Affairs and Communications under postal laws and ordinances when providing letter postal and international parcel postal delivery services by the postal services business. Also, domestic parcel delivery services, now provided as “postal parcel delivery services,” should be excluded from the obligation of postal services business from the beginning of the privatization transition period and should be supervised by the Minister of Land Infrastructure and Transport under freight transportation laws and ordinances. As for tax payment, the same taxation system should be applied to the Postal Service Company as that of other private companies, except for the minimum necessary measures for the smooth transition and succession of business and



functions of Japan Post.

- b. With regard to cross-subsidization, under the current Postal Service Law, the status of profit and loss is already disclosed according to the categories of letter postal items, parcel postal items, and international postal services. The privatization laws provide that the current measures regarding the public disclosure of the status of profit and loss according to the categories should be maintained (domestic postal parcel delivery services will be excluded from “postal services”). In addition, the Postal Service Company should disclose the status of profit and loss according to the categories of postal services business and other newly privatized business areas, including domestic and international logistics business to the same standards of the Generally Accepted Accounting Principles as required of other private companies. The privatization laws do not provide for any scheme to allow unfair cross-subsidization between the postal services business regulated by the Minister of Internal Affairs and Communications and the parcel delivery and newly established logistics business regulated by the Minister of Land Infrastructure and Transport (for example, income transfer from monopoly services to other competitive businesses would not be allowed).

3. Transparency:

- a. The Office for Privatization of Japan Post (OPJP) and Ministry of Internal Affairs and Communications (MIC) have ensured openness and transparency by providing in a timely manner meaningful opportunities for private sector interested parties upon request to exchange views with relevant officials, steps that have been welcomed by the Government of the United States. The OPJP and its succeeding bodies, MIC and FSA will continue to provide opportunities for private sector interested parties, upon request, to exchange views with relevant officials.
- b. The Government of Japan recognizes the importance of transparency in the privatization process, including informing the general public of any laws, regulations, guidelines, and other substantive aspects of postal services privatization through appropriate methods. With respect to the preparation and implementation of administrative rules, administrative official decisions and administrative guidelines, the Government of Japan will ensure transparency through the necessary use of procedures in accordance with the amended Administrative Procedure Law and other measures, including providing in a timely manner meaningful opportunities upon request for private sector interested parties to exchange views with relevant officials of the Government of Japan. The Government of Japan recognizes the importance of transparency of the PSPC, and therefore will take appropriate measures accordingly. Issues arising from the implementation of the privatization laws will also be

further addressed in a manner described in the last paragraph of the preface of this Report.

## IX. LEGAL SYSTEMS REFORM

### A. Ensuring Freedom of Association for Foreign Lawyers

1. The amended Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers (*Gaiben* Law) came into force on April 1, 2005. This amendment introduces completely new mechanisms for association between Japanese lawyers (*bengoshi*) and registered foreign lawyers (*gaiben*), including provisions that lift the ban on employment of *bengoshi* by *gaiben*, abolish the system of specified joint enterprises (*tokutei kyodo jigyo*), and introduce the system of joint enterprises between *bengoshi* and *gaiben* (*gaikokuho kyodo jigyo* or “GKJ”).
2. The Japan Federation of Bar Associations (*Nichibenren*) has established rules and regulations for implementation of the amended *Gaiben* Law, including those for the employment of *bengoshi* by *gaiben* and for the GKJ. Through discussions with *Nichibenren*, the Ministry of Justice (MOJ) has made efforts to seek *Nichibenren*'s better understanding of the amended *Gaiben* Law and to request appropriate handling of the related procedures within respective bar associations so that *Nichibenren* would be able to make its rules and regulations consistent with the basic concepts and interpretation of the amended *Gaiben* Law.
3. With respect to concerns related to interpretation of the *Gaiben* Law expressed by the Government of the United States, it is the view of MOJ that a *gaiben* partner who employs a *gaiben* associate with a different scope of competence from that *gaiben* partner can accept and handle legal business to be handled by that *gaiben* associate on the condition that Article 5-2 (legal business concerning the third country law) of the *Gaiben* Law is followed.
4. MOJ will, as necessary, discuss with *Nichibenren* the appropriate handling of its rules and regulations so that its rules and regulations are consistent with the views of MOJ.

- B. **Permitting Professional Corporations and Branches:** The MOJ will diligently study whether *gaiben* should be permitted to form professional corporations and branch offices from the standpoint of trends in international legal services and principles of non-discrimination. In particular, MOJ is now studying the practical considerations that must be addressed if *gaiben* were to be permitted to establish professional corporations or if *gaiben* and foreign law firms were to be permitted to establish branch offices without forming a separate Japanese legal professional corporation, in light of the actual operation of the GKJ and *bengoshi* professional corporations, and other laws and regulations.

## C. Promoting Alternative Dispute Resolution

1. The Government of Japan has been studying ways to strengthen and revitalize alternative dispute resolution (ADR) in Japan, including ways to create a flexible and open legal environment that will facilitate the development of ADR services, so that ADR could become an equally attractive option to court litigation as a means of dispute settlement, on the recognition that ADR mechanisms can play an important role in helping individuals and businesses resolve disputes in an efficient and economical manner. As a result, the Law for the Promotion of the Use of Alternative Dispute Resolution (ADR Law), enacted in 2004, will allow for the promotion of ADR in a manner that is consistent with international norms and practices as follows:
  - a. The criteria under the ADR Law for certification by the Minister of Justice of ADR services covered by chapter 2 of the ADR Law (hereinafter referred to as “ADR services”) are minimal. Furthermore, certification for ADR services by ADR providers will be completely voluntary and open to Japanese and foreign nationals on an equal basis. The ADR Law does not restrict the ability of providers of ADR services that are not certified to continue to operate their business or of new ADR providers to establish new businesses without obtaining certification.
  - b. Parties will be allowed, as a general matter, to determine the rules, process and standards to be applied in individual ADR proceedings.
  - c. ADR services that have received certification under the ADR Law are not considered to be in violation of Article 72 of the Lawyers Law. Similarly, acting as a neutral for pay in ADR services by a person who is not a *bengoshi*, even if the ADR services provided by that person are not certified, is not considered to be a violation of Article 72, where acting as a neutral is just from a social viewpoint. Moreover, acting as an arbitrator in accordance with the Arbitration Law is also considered not to be a violation of this Article.
  - d. Where persons who are not *bengoshi* act as neutrals in certified ADR services, there will be no general requirement that a *bengoshi* supervise the ADR process. Instead, there should be a system in place to obtain legal advice from a *bengoshi* where necessary.
  - e. In addition, both *gaiben* and foreign lawyers, as well as *bengoshi*, are permitted to provide services of representing a party in international arbitration proceedings that take place in Japan. The Government of Japan confirms that *gaiben* are permitted to provide representation services in ADR proceedings (other than arbitration proceedings, which are covered by Article 5-3 of the *Gaiben* Law) within the scope of their functions.

2. The ADR Law will come into effect no later than May 31, 2007. It provides that the central and local governments will be responsible for providing information to familiarize the public with ADR in order to promote the use of all kinds of ADR. In elaborating ministerial ordinances and guidelines for the implementation of the ADR Law, the Government of Japan will ensure that the ADR Law is implemented in a manner that takes into account trends of international discussions, norms and practices, and that the procedures for obtaining certification, and any post-certification reporting requirements, are reasonable and not unduly burdensome. In this regard, the Government of Japan will:
  - a. Ensure that the Public Comment Procedure is used for all ministerial ordinances and guidelines implementing the ADR Law; and
  - b. Monitor closely, once the ADR Law comes into effect, the effects of the ADR Law on ADR proceedings involving cross-border or e-commerce disputes and take action without delay to remedy any problems or impediments to such ADR proceedings that come to light.

## **X. COMMERCIAL LAW**

- A. **Adoption of Modern Merger Techniques:** The Government of Japan has been promoting the restructuring of the Japanese industry in various ways, such as the revision of the Industrial Revitalization Law, which was enacted in April 2003. On March 22, 2005, the Government of Japan submitted to the Diet the Corporate Code Bill, which introduces flexibility in merger currency to permit the use of triangular mergers, cash mergers and exchanges of foreign shares as well as allows short-form (squeeze-out) mergers. This Bill was passed by the House of Representatives on May 17, 2005 and by the House of Councilors on June 29, 2005. Most of the amendments to the Corporate Code will come into effect on the date specified by Cabinet Order, and the provisions introducing flexibility in merger currency will come into effect one year later.
  1. The Government of Japan will take the necessary steps to ensure that the amendments come into effect as soon as possible.
  2. The Government of Japan is convinced that these new provisions will facilitate M&A transactions, and therefore will benefit the Japanese economy.
  3. The Government of Japan is studying tax treatment of triangular mergers available under the Corporate Code, including consideration of the appropriateness and equity of taxation, the prevention of tax avoidance -- and the Government of the United States points out that tax considerations are crucial for companies in determining whether or not to participate in an M&A transaction -- with the intention of adopting such policy by such time as relevant sections of the Corporate Code go into effect.

4. The Government of Japan will encourage corporations to refrain from adopting or invoking anti-takeover measures that do not have as their purpose and effect the maximization of shareholder value or that have as their primary objective the protection of entrenched management. In that regard, on May 27, 2005, the Ministry of Economy, Trade and Industry and the Ministry of Justice jointly issued “Guidelines Regarding Takeover Defense for the Purposes of Protection and Enhancement of Corporate Value and Shareholders’ Common Interests” to that end.

**B. Promoting Shareholder Value through Active Proxy Voting**

1. Promote Sound Proxy Voting Policies by Pension Funds: The Government of Japan recognizes the important role of active shareholder voting in strengthening corporate governance and shareholder value to the benefit of the beneficiaries of pension funds. In this light, the Government of Japan supports the promotion of proxy voting by managers of public and private pension funds as a mechanism for increasing investment returns to pension funds. Over the past year, the Government of Japan has pursued the following policies and taken the following actions in this regard:
  - a. The Government Pension Investment Fund (GPIF) supports transparency in the proxy voting policies and actual voting record of its fund managers. In that regard, GPIF has previously issued the Investment Management Policy applicable to all of its pension fund managers requiring them to exercise proxy voting rights to maximize shareholder value and to report to GPIF annually on their actual record of proxy votes. In October 2004, the results of the exercise of proxy voting rights by fund managers were made public. Proxy voting rights were exercised by all fund managers in 2004.
  - b. A number of GPIF’s fund managers have publicly disclosed their proxy voting policies on a voluntary basis. GPIF will encourage all of its fund managers to disclose their proxy voting policies, as it continues to study whether its Investment Management Policy should be revised to require such disclosure.
  - c. With regard to private pension funds, the Government of Japan supports the continued development of fiduciary duties for pension fund managers with respect to the exercise of proxy voting rights, and will undertake a study to examine whether adoption of a specific fiduciary duty for the exercise of proxy voting rights is appropriate, in light of developments in international practice in this area.
2. Encourage Disclosure of Proxy Voting Records by Mutual Funds:

- a. The Government of Japan supports the promotion of proxy voting by mutual fund and investment trust managers as a mechanism for increasing corporate value. The Financial Services Agency (FSA) is currently encouraging the Investment Trust Association to amend its rules on proxy voting to also require members to publicly disclose their actual proxy voting record.
  - b. FSA confirms that the Law for Investment Trust and Investment Companies requires that the actual proxy voting record of investment trust management companies be recorded in the official records of such companies and that beneficiaries of those investment trusts be allowed to review those records.
3. Facilitate Proxy Voting by Foreign Shareholders: In response to a request made by the Government of the United States regarding proxy voting by foreign shareholders, the Government of Japan confirmed the following:
- a. Under the Commercial Code of Japan, there is no provision that restricts proxy voting by foreign shareholders. A global custodian or subcustodian of foreign proxies may exercise some of its granted voting rights in favor of a certain proposal and the rest of its granted voting rights to another or contrary proposal.
  - b. Article 22 (2) of the Investment Trust and Investment Corporation Law treats foreign companies and Japanese companies the same, where the foreign company is established in accordance with a foreign law, is the same kind of corporate body as that stipulated by the Commercial Code of Japan and has a sales office in Japan.
  - c. The Government of Japan will continue to consider the role of the Tokyo Stock Exchange (TSE) to enhance the corporate governance of its listed companies including a review of TSE rules to take into account the growth of the number of foreign shareholders.

## **XI. DISTRIBUTION**

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

1. The Government of Japan expressed its views on the concerns held by the Government of the United States regarding landing and user fees at Narita, Kansai and Chubu International Airport.
2. The 2005 management plan of Narita International Airport Corporation (NAA), announced in April 2005, commits the corporation to the reduction of landing fees as one of the most important strategies. On June 2, NAA began consultations with IATA for the reduction of landing fees, and on September 16 they

announced the new set of negotiated user charges, which has been applied since October 1. Landing fees of NAA have been reduced by 21 percent on average, with the introduction of some new fees for other services. NAA estimates that these changes will reduce their revenue by 11 percent in total. The new landing charges are determined according to aircraft noise level and, therefore, the exact percentage of reduction of landing fees varies for each airline.

3. The Government of Japan welcomes NAA's proposed reduction of landing fees.
4. 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.

**B. Airfares:** The Government of Japan expressed its views on the concerns of the Government of the United States regarding Airline Sales Distribution and 30-Day Advance Fare Filing Requirement.

**C. Credit/Debit Cards**

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 MIC is considering several aspects, including legal and technical, of introducing card payment for local government services. Based on these considerations, MIC will reach a conclusion on the matter by the end of FY2005, as provided for in the revised Three-Year Program for the Promotion of Regulatory Reform.

**D. Revision of the Road Transportation Vehicle Law**

1. To facilitate registration and title transfer procedures, the Office of the Trade and Investment Ombudsman (OTO) recommended in March 2005 a review of the Road Transportation Vehicle Law (RTVL) and its implementation.

2. The Government of Japan will further consider the possibility of taking measures to lighten the burden on vehicle leasing companies with regard to procedures related to vehicle registration.



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

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

**A. Consular Affairs**

1. Use of Biometric Identifiers on Passports:

- a. Reliable and secure travel documents are a key component of border security. The Government of the United States welcomes the efforts of all countries to issue more secure passports. The Department of State, in a September 26, 2004 letter, certified that the Government of Japan met the requirement of the Border Security Act to have a program in place to produce biometrically enabled passports.
- b. The Government of the United States recognizes that the Government of Japan has been active in moving forward with its advanced biometric passport program, and particularly takes note that the Bill to amend the Passport Law passed the Japanese Diet and was enacted on June 3, 2005 in an effort to start issuing biometrically enabled passports in March 2006.
- c. The Government of the United States announced on June 15, 2005 that Visa Waiver Program (VWP) countries will be required to produce passports with digital photographs by October 26, 2005. On that date, all VWP countries must also present an acceptable plan to issue passports with integrated circuit chips, or e-passports, within one year. The Department of State remains committed to the biometric passport as the safest possible travel document, and will continue to work with the VWP countries on its development. The Government of Japan welcomed this announcement June 15, 2005, because Japan's participation in the VWP is important to maintaining active interaction between the people of Japan and the people of the United States. Following the June 15 announcement and in accordance with the more specific requirements presented by the Government of the United States for VWP countries, the Ministry of Foreign Affairs of Japan submitted a letter dated July 29, 2005, as notification that the Government of Japan adequately fulfils the requirements. The Department of Homeland Security confirmed in its letter of September 15, 2005 that Japan is certified for the requirements to retain VWP status.

2. VWP Requirement Regarding Machine-readable Passports:

- a. Although the U.S. Immigration and Nationality Act originally set October 1, 2003 as the date by which Visa Waiver Program (VWP) travelers were required to present an individual machine-readable passport for visa-free travel to the United States, the majority of VWP countries, including Japan, requested and were granted a postponement of this requirement for more than a year to October 26, 2004.
  - b. For a limited period that started on October 26, 2004, U.S. Customs and Border Protection (CBP) officers at U.S. borders and ports of entry could exercise discretion to grant a one-time entry at no charge for VWP travelers arriving without an individual machine-readable passport. Japanese travelers carrying non machine-readable travel documents benefited for eight months from this discretionary waiver as requested in the Government of Japan's recommendations.
  - c. Although this limited period ended on June 26, 2005, the Department of State has been working closely with VWP countries to communicate information about the machine-readable passport requirement to their citizens. Since October 26, 2004, CBP officers have been notifying VWP travelers entering the United States with a letter explaining the machine-readable passport requirements. CBP issued a reminder on June 6, 2005 to all travelers from the VWP countries about the new requirement. The Government of the United States will continue to work with the Government of Japan to assist travelers with non machine-readable travel documents on a case-by-case basis when true emergencies arise.
  - d. Outreach efforts to inform the public of the June 26, 2005 deadline have helped reduce the number of VWP visitors arriving in the U.S. without the proper passport. Outreach efforts have also been made to inform VWP countries of the requirement that, from October 26, 2005, new passports issued by VWP must include a digital photo, or the traveler will be required to obtain a visa.
3. Immigration Control by Use of Biometric Identifiers at Ports of Entry:
- a. US-VISIT is a top priority for the U.S. Department of Homeland Security because it enhances security for citizens and visitors while facilitating legitimate travel and trade across U.S. borders.
  - b. US-VISIT entry procedures are currently in place at 115 airports, 15 seaports and in the secondary inspection areas of the 59 busiest land ports of entry. US-VISIT exit procedures are operating at 12 airports and 2 seaports. Entry procedures will be deployed to the remaining land ports of entry by December 31, 2005.

- 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 the border management system by planning tests of radio frequency identification (RFID) technology at the U.S. land borders. As of October 2005, over 39 million foreign visitors have been processed, and there has been no significant increase in wait times attributed to US-VISIT. Wait times are continually monitored as part of daily Port operations. US-VISIT procedures take just seconds. Post-implementation reviews from the pilot testing at three of the busiest land ports of entry: Douglas, Arizona; Laredo, Texas; and Port Huron, Michigan, show that US-VISIT deployment is in almost every case expediting processing times for those visitors who require a Form I-94 and are therefore subject to US-VISIT procedures. Prior to US-VISIT, the average inspection time at Laredo's secondary inspection area was approximately 11 minutes. Results from Laredo indicate that the process now takes less than five minutes and, in many cases, as little as two minutes. DHS will continue to monitor the situation of air, sea and land ports of entry to ensure that it has adequate human, physical and technological resources to fully and efficiently implement US-VISIT.
- d. US-VISIT meets regularly with the Government of Japan through its Embassy in Washington, DC. 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 requirements of the US-VISIT program and what to expect when entering or exiting the United States. This effort has been in place since early 2004 and will continue. In addition to the list below, US-VISIT participated in the "See America Week Japan" program in Tokyo, Nagoya, and Osaka in September 2005. That program included a "Media Marketplace" for outreach to local media.
- e. In December 2003, DHS launched a public information outreach campaign which has included: paid advertisements in major Japanese media which collectively reach over 10 million people in Japan, distribution of an animated in-flight video for airlines in Japanese, pamphlets in Japanese and instructional signage in Japanese. US-VISIT also attended meetings with travel and tourism stakeholders and a media roundtable (November 2004, Tokyo), Visa Waiver Program Announcements (September 27, 2004, Los Angeles and Dulles International Airports), and international travel and tourism trade shows such as the Travel and Industry Association Pow Wow (April 2004, Los Angeles) and World Travel Market (November 2004, London). SeeAmerica, developed by the Travel Industry Association of America (TIA) in the absence of a federally-funded national tourism promotion agency, also seeks to inform travelers of US-VISIT and other requirements.

- f. 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.
- g. At land ports of entry, a Japanese national with a visa would only experience US-VISIT procedures once for each multiple entry Form I-94 they apply for. If the I-94 were good for one year, then the person would only go through US-VISIT again upon the expiration of the original document.
- h. The Government of the United States fully understands the Government of Japan's concerns about protecting the information of Japanese citizens obtained through the new biometric requirements. 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. The Government of the United States protects the biometric identifiers of foreign nationals collected by US-VISIT under the same level of privacy standards as those applied to United States citizens' personal information. Safeguards have also been implemented to ensure that the data is not used or accessed improperly. The DHS privacy officer will review pertinent aspects of the program to ensure that proper safeguards are in place.

4. Visa Process:

- a. *Introduction of Visa Services into the Other Consulates in Japan:*
  - (1) The computerized appointment system that permits visa applicants to schedule appointments over the Internet without a fee has contributed to greater efficiency for Japanese applicants. Since the commencement on August 1, 2003, of the requirement to interview all visa applicants, the Department of State has increased staffing in the visa sections in Tokyo by five officers, Osaka by three officers, and Naha by one officer. The Government of the United States will continue to monitor whether the appointment system is functioning effectively and whether the number of staff stationed

in Japan for visa services is sufficient to process visa applications without backlog.

- (2) The Government of the United States continues to consider the request by the Government of Japan that the United States Consulates in Fukuoka and Sapporo should resume visa services, and to take note of its request that the United States Consulate in Nagoya should open visa services. The United States remains committed to making continued improvements in the visa process, including expanded uses of technology that leverage the power of biometrics.

b. *Efficiency in Visa Revalidation Procedures:*

- (1) Serious concerns have been raised by the Japanese business community operating in the United States, as well as by the Government of Japan, about the increased burden incurred by the suspension of business visa revalidation in the United States. While visa validity is not linked to the eligibility of visa holders to stay in the United States, in reality, it is somewhat inconvenient for businessmen to have their visas revalidated while on business trips to the neighboring countries of the United States or to their home country. Scheduling of business trips is often decided on short notice and a tight schedule in their destination sometimes does not allow them to appear at United States Embassies and Consulates for visa revalidation. Bearing in mind this difficulty, the Government of the United States will continue to consider the resumption of visa revalidation in the United States.
- (2) The Government of the United States is deeply 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. The Government of the United States and the Government of Japan engage in regular working level dialogue on visa issues.

c. *Visa Issuance and Terms of Validity:*

- (1) While the United States encourages all visa applicants to apply for visas in their home countries, it is possible to apply at some third country posts, provided the post is able to accommodate an interview appointment request. The Department of State has initiated a new feature on its website which gives useful estimates of “visa wait times” at all diplomatic posts around the world. Some posts do not currently offer E-visa revalidation for third country nationals. However, the Department of State is reviewing

staffing and resource allocations at all visa processing posts, and will carefully and seriously consider Japan's request that its nationals be allowed to revalidate E-visas at posts in Canada and Mexico.

- (2) The number of H-1B visas issued annually is set by the Congress. The current cap is 65,000. In the Omnibus Appropriations Act for 2005 (HR 4818) an additional 20,000 H-1B visas were authorized that will not count against the cap. These are for individuals who received higher level degrees in the United States.
- (3) HR 4818 also contained several provisions relating to H-1B and L-1 visas. For L-1 visas these include restrictions on the stationing of L-1 workers at third party sites under the control of the third party and extending the length of continuous employment required for employees covered by blanket petitions to 12 months. H-1B employers are now required to pay 100 percent of prevailing wage. Other provisions relate to the prevention of fraud in these categories, including the establishment of a fraud prevention fee of \$500. Several bills from the 108th Congress (H.R. 2154, H.R. 2702, and H.R. 2849) about which the Government of Japan had expressed concern were not enacted.
- (4) The Government of the United States seriously considers 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 intracompany transferees to Japan are provided with five-year visas.
- (5) The Government of the United States recognizes that facilitation of E visas is important to the Government of Japan and acknowledges its request concerning the requirements to be qualified for E visa.

5. Driver's License:

- a. The Real ID Act, signed into law by President Bush on May 11, 2005 and which will go into effect in three years, requires the Department of Homeland Security (DHS) to issue regulations that will establish the minimum standards for State governments to follow when issuing driver's licenses or other forms of State-issued identification. The Real ID Act requires that the States collect certain biographic information about each individual applying for a driver's license, including full name, date of birth, and address of principal residence. The Act prohibits federal agencies from accepting for any official purpose a state-issued identification card or driver's license that does not meet the minimum standards that DHS will issue.

- b. In addition, all States must enter into a Memorandum of Understanding (MOU) with DHS to verify the legal presence of all noncitizen driver's license applicants. Most States entered into the MOU with DHS required by the Real ID Act by September 11, 2005 to routinely use the Systematic Alien Verification for Entitlements (SAVE) to verify a driver's license applicant's lawful status. The MOU, however, did not require a State entering the MOU to begin using SAVE in 2005. For all noncitizens authorized to be in the United States for a temporary period, the validity period of a driver's license or identification card issued by the State may not exceed the period of authorized stay.
- c. Individuals who hold driver's licenses or personal identification cards from States that are not in compliance with the law cannot use that license for federal identification or other official federal purposes, for example, to enter federal buildings or fly on planes. States are not prohibited from issuing a "driving certificate" valid for driving but not for federal identification purposes, as States such as Tennessee and Utah have already done. Use of foreign passports to board airplanes would still be permitted.
- d. 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. The Government of the United States understands the concerns raised by that the Government of Japan that the new law may impact foreign citizens, including Japanese nationals residing in the United States. DHS will 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 that will take place after publication of a Notice of Proposed Rule-Making.
- e. A new Illinois law (Public Act 93-0752), which went into effect on January 1, 2005, allows the state to issue "Temporary Visitor Drivers Licenses" to foreign citizens who are living in Illinois legally, but are ineligible for a SSN. A detailed explanation of the procedures is available on the Illinois Secretary of State website. [www.ilsos.net/departments/drivers/drivers\\_license/tempvisitordl.html](http://www.ilsos.net/departments/drivers/drivers_license/tempvisitordl.html). At this time it is the understanding of the Government of the United States that, with the change in Illinois law, all the States now accept an alternative identifier for a SSN for driver license purposes.

- f. 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, and State of Tennessee driver's certificates.

6. 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.

- 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.

7. Permission to Stay (I-94):

- a. *Longer Terms of Validity of I-94:* The Government of the United States confirms that by Federal Regulations, CBP immigration officers have the authority to admit E visa holders for an initial period of not more than two years as long as the remaining validity period of their passports is sufficient.

- b. *Swifter Processing of I-94 Extension:*

- (1) 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.
- (2) USCIS has set the agency's priorities as (1) ensuring national security, (2) reducing the backlog, and (3) improving customer service. In the agency's first two years, 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.

## **B. Trade/Investment Related Issues**

1. Anti-Dumping Measures and Safeguard Measures:
  - a. The Government of the United States will ensure that its anti-dumping laws conform to its WTO obligations. In that regard, the Administration supports legislation that would bring relevant provisions of the Continued Dumping and Subsidy Offset Act (CDSOA) into compliance with WTO recommendations and rulings. In addition, the Administration will continue to work closely with Congress on legislation to implement the WTO recommendations and rulings in the Hot-Rolled Steel dispute.
  - b. Legislation has been introduced in the 109th Congress that would bring United States law into conformity with WTO obligations with respect to the CDSOA and Hot-Rolled Steel disputes.
  - c. Section 801 of the U.S. Revenue Act of 1916 (Anti-dumping Act of 1916) was repealed on December 3, 2004.
  - d. 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 and safeguard measures and practices.
2. The Patent System of the United States: The Government of the United States and the Government of Japan reaffirm mutual support for effective substantive patent law harmonization efforts, and at the same time:
  - a. The Government of the United States will continue to discuss with the Government of Japan its concerns with the United States' first-to-invent patent system. The United States acknowledges that its first-to-invent system is unique, but believes that the system has worked well in and for the United States. While there is some growing interest in first-to-file, as reflected in legislation currently pending in the U.S. Congress (H.R. 2795 and proposed amendments thereto), this remains a controversial issue in the United States. Outside of the proposed legislation, the U.S., Japan, and other WIPO Group B members have also been engaged in talks on patent law harmonization, in which the draft provisions being discussed are written from a first-to-file perspective. The United States will continue to pursue these discussions.
  - b. The Government of the United States will continue to discuss with the Government of Japan its requests regarding abolition of the exceptions to

the publication of patent applications within 18 months from the filing date found in the U.S. early publication system. The United States hopes that its experience with the early publication system will reveal that the need for exceptions will be proven to be unwarranted. This issue is also addressed in the above-referenced legislation.

- c. The Government of the United States will continue to consider the requests of the Government of Japan regarding further improvements of the reexamination system. Changes to the U.S. reexamination system, as well as new provisions for post-grant opposition proceedings, are also addressed in the above-referenced legislation.
- d. The Government of the United States will continue to consider the requests of the Government of Japan to ease requirements for the unity of invention. It should be noted that the United States is currently studying adoption of a Unity of Invention standard.
- e. The Government of the United States will continue to discuss with the Government of Japan its requests to modify the Hilmer Doctrine. The United States would like to note that this issue is being discussed in the ongoing substantive patent law harmonization talks between the U.S., Japan, and other WIPO Group B members. This issue is also addressed in the above-referenced legislation.
- f. The Government of the United States notes the issue raised by the Government of Japan concerning the determination of novelty as provided for under U.S. plant patent law and the UPOV convention. The Government of the United States notes the concern expressed by the Government of Japan and will take the issue under consideration.

3. Insurance Business Regulations:

- a. The National Association of Insurance Commissioners (NAIC) continues to implement its 2003 Regulatory Modernization Action Plan that includes steps to promote interstate cooperation and enhance efficiency. Concrete progress includes:
  - (1) Development of a company licensing model act to establish standardized filing requirements for license applications and uniform licensing standards, which has been adopted by all states;
  - (2) Creation of a single point electronic filing system, which is now in use by 49 states and the District of Columbia; and

(3) Implementation of the Interstate Insurance Product Regulation Compact covering life, annuity, disability, and long-term care products, currently adopted by 15 states.

- b. The Government of the United States is aware that the Government of Japan has expressed some concerns with respect to certain state insurance regulations and procedures. The Government of the United States has conveyed these views to NAIC, and the NAIC has in turn conveyed these views to the appropriate state regulators. 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.
- c. Issues involving reinsurance collateral requirements continue to be discussed within the NAIC's Reinsurance Task Force. The Task Force has met regularly, and its meetings are announced on the NAIC's website. Interested parties have been able to attend these meetings freely. The Task Force is currently working on a white paper to provide a comprehensive overview of U.S. reinsurance requirements applicable to unauthorized reinsurers, and the proposals that have been presented to the Task Force for consideration of revising the current collateral rules.

4. Harmonization of State Environmental Regulations:

- a. The federal Environmental Protection Agency (EPA) understands the concerns of the Government of Japan regarding harmonization of the environmental regulations of individual States.
- b. EPA and the individual States share responsibility for environmental protection and work as partners to solve the nation's environmental challenges. One approach to this partnership is the National Environmental Performance Partnership System, the goal of which is to build an environmental management system focused on achieving the best results possible, taking full advantage of the unique strengths of each partner. By promoting and sharing best results, the program can help to improve the consistency of State regulatory approaches.
- c. EPA is also taking steps to highlight and promote successful State approaches concerning mercury switches and other items of concern, which should help to harmonize State approaches. As an example, EPA is amending the federal Universal Waste Rule to include mercury applications, which will ease the recovery of mercury switches. Many States will automatically adopt the new federal regulations on the State level, and EPA will work with all States to encourage the adoption of this new standard. EPA also provides links to all State universal waste

programs on the EPA website.

<http://www.epa.gov/epaoswer/hazwaste/id/univwast/uwsum.htm>

- d. In the field of electronics, EPA is working very closely with key stakeholders, including States, to encourage reduced use of mercury in computer desktops, laptops, and monitors through the development of the Electronic Products Environmental Assessment Tool (EPEAT). More information on this environmental procurement tool can be found at the following website: [www.epeat.net](http://www.epeat.net).

## C. **Distribution**

### 1. Counterterrorism Measures in Physical Distribution:

- a. *Transport Security:* The Government of the United States shares an understanding with the Government of Japan on the importance of balancing security considerations with the need to facilitate international trade. This can be achieved through international cooperation in setting consistent practices and common procedures. The Government of the United States played an important role in working with the International Maritime Organization (IMO) to develop the International Ship and Port Facility (ISPS) Code which has set a common standard for assessing ship and port facility security. The Government of the United States, through the High Level Strategic Group, is currently working with the World Customs Organization (WCO) to implement the *Framework of Standards to Secure and Facilitate Global Trade*. This framework will secure trade in such a way that it will also facilitate the commerce that is essential to economic prosperity.

- (1) Advance electronic presentation of cargo information: The Government of the United States has worked very closely with the international trade community as the regulations implementing the advance electronic cargo information for the Trade Act were developed. It is important that governmental information requirements to support risk assessments are properly aligned with the business process to ensure accurate and timely information without placing an undue burden on the trading community. International consistency is one method of limiting the impact. The Government of the United States welcomes the opportunity to work with the WCO to move toward greater international uniformity in cargo data requirements. The Customs-Trade Partnership against Terrorism (C-TPAT) is an industry and government partnership to improve overall supply chain security. It is a voluntary program to implement security criteria and best practices that better protect the entire supply chain against exploitation by terrorists. In exchange for voluntarily

implementing security criteria, C-TPAT participants are eligible for a number of benefits including a reduced level of inspection of their cargo. Our review has shown that C-TPAT participants receive significantly fewer cargo inspections than non-C-TPAT importers. It should be noted that C-TPAT members are 6 times less likely to undergo a security related inspection, and 4 times less likely to undergo a trade related inspection, as compared to non-C-TPAT members. There are clearly financial benefits as a result of these fewer inspections. The Government of United States welcomes discussions with the Government of Japan and explores further advantages for C-TPAT members. The Government of United States 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) Automated Commercial Environment: The Automated Commercial Environment (ACE) will be implemented over a multi-year system development cycle. ACE is designed to meet the evolving needs of both the United States government and the trade community. System wide enhancement now and in the coming years will create increases in efficiency and the reduction of paperwork. An important milestone is the implementation of the electronic manifest which will support advance electronic cargo information for trucks arriving from Canada and Mexico. This e-manifest system is currently being field tested prior to large scale implementation. This will support the implementation of the electronic advance information requirements of the Trade Act. Automated manifest systems already exist for rail, air, and vessel.

b. *The Bioterrorism Act and Related Regulations:*

- (1) The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act or the Act) (PL 107-188), authorized the U.S. Food and Drug Administration (FDA) to develop rules, after notice and an opportunity for domestic and international stakeholders to comment, 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 March 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.

- (2) The United States notes that FDA's "Compliance Policy Guide" initially published in December 2003 (and most recently revised in March 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/cpgpn5.html>.
- (3) 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, work to 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.

## 2. Container Weight Limits:

- a. 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 container weight limits. FHWA's FMO oversees individual State enforcement of Federal size and weight standards for heavy trucks and buses in the United States, as set by Congress. FHWA provided detailed guidance on commercial vehicle weight limits in the United States.

- b. In summary, federal weight laws, effective on the National System of Interstate and Defense Highways and reasonable access thereto, establish commercial vehicle limits on the basis of axle weight, gross vehicle weight, and the bridge formula weight (spacing of axles along the vehicle and the effect that has on load distribution). The U.S. does not set weight standards for cargoes or the boxes in which they move, but rather, the total vehicle combination and its relative axle weights. The maximum gross vehicle weight on Interstate highways is 80,000 pounds except where lower gross vehicle weight is dictated by the bridge formula.
  - c. States also 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 defines the significantly heavier Japanese container movements as non-divisible loads, a State can issue an overweight permit allowing the loads on the Interstate. A State would have to determine if it were willing to accept (and physically capable of handling) the accelerated infrastructure damage from such loads in determining whether to grant them non-divisible status.
  - d. 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.
3. 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.
4. Maritime Security Program: The Government of the United States took note of the request of the Government of Japan to abolish the Maritime Security Program.

- a. The Maritime Security Program (MSP) is intended to ensure that an active U.S. merchant fleet and the trained personnel needed to operate both active and reserve vessels will be available to meet U.S. national and global security requirements for sealift capacity. On November 24, 2003, the President signed the National Defense Authorization Act for Fiscal Year 2004, which contained the Maritime Security Act of 2003 (MSA 2003), creating a new MSP for up to 60 ships for fiscal years 2006 through 2015. The new 10-year program begins October 1, 2005 and authorizes \$156 million annually for FY 2006-2008; \$174 million annually for FY 2009-2011; and \$186 million annually for FY 2012-2015.
  - b. The Government of the United States will ensure that the Government of Japan is kept informed of the list of the dedicated vessels and any changes in the MSP. The Government of the United States believes the MSP is important to meet global security needs at this time.
5. 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.

#### 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.

- b. The United States again notes that the scope of the law 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 the missiles capable of delivering them.

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 July 15, 2005, the President sent a letter to Congress consistent with the Act to suspend for six months beyond August 1, 2005, 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. The Antitrust Modernization Commission (AMC) was established on April 2, 2004, pursuant to the Antitrust Modernization Commission Act of 2002.
  - a. The Commission is charged by statute with:
    - (1) Examining whether the need exists to modernize the antitrust laws and to identify and study related issues;
    - (2) Soliciting views of all parties concerned with the operation of the antitrust laws;
    - (3) Evaluating the advisability of proposals and current arrangements with respect to any issues so identified; and

- (4) Preparing and submitting to Congress and the President a report containing a detailed statement of the findings and conclusions of the Commission, together with recommendation for legislative or administrative action the Commission considers to be appropriate.
  - b. At its January 13, 2005, meeting the AMC decided to examine, among other matters, the following issues related to antitrust immunities and exemptions, and in May 2005 solicited public comment on detailed questions related to certain of those issues:
    - (1) Should antitrust immunities and exemptions be eliminated if not justified by the benefits they provide, or should they otherwise be time-limited?
    - (2) Should the antitrust exemptions for exporters set forth in the Webb-Pomerene Act and Title III of the Export Trading Company Act be eliminated?
    - (3) Should the state action doctrine be clarified or otherwise changed?
    - (4) Should the Noerr-Pennington doctrine be clarified or otherwise changed?
  - c. On March 31, 2005, the AMC released a projected timetable for its work. According to that timetable, the AMC will submit its final report to Congress and the President in April 2007.
2. The Government of the United States' antitrust agencies 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.
  - a. In that regard, in June 2004, the United States filed an *amicus curiae* brief with the U.S. Court of Appeals for the Sixth Circuit in Jackson, Tennessee Hospital Co. v. West Tennessee Healthcare, Inc. arguing that subordinate state entities, such as municipalities and hospital districts, may claim "state action" exemption from the Sherman Act only if they can demonstrate that their anticompetitive activities were authorized by the State pursuant to state policy to displace competition with regulation or monopoly public service, and that mere authorization to do business like a private firm does not amount to the requisite authorization.
  - b. Also, in December 2004 the United States, in U.S. v. Gosselin World Wide Moving N.V., filed a brief with the U.S. Court of Appeals for the Fourth Circuit arguing that the antitrust immunities provided by the Shipping Act of 1984 should not be construed to apply to rigging bids on

through rates paid by the Department of Defense to transport military and civilian household goods to the United States.

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

1. Acceptance of Foreign Lawyers as Foreign Legal Consultants:

- a. In August 2002, the American Bar Association (ABA) adopted a resolution to encourage all states to adopt foreign legal consultant systems based on the ABA's Model Rule. Since that time, the ABA has continued to work diligently to increase the number of states that have foreign legal consultant systems consistent with its Model Rule. In that regard, in 2005 the ABA's Joint Committee on Lawyer Regulation met with state bar leaders, worked with the Conference of Chief Justices and provided consultations services to a number of states regarding implementation of the Model Rule.
- b. In response to the ABA's efforts, in 2005 the states of Pennsylvania and Idaho adopted foreign legal consultant systems based on the ABA Model Rule. Moreover, the state of Georgia revised its foreign legal consultant system to make it equivalent to the ABA Model Rule. These actions bring to 26 the number of U.S. jurisdictions that permit Japanese and other foreign lawyers to practice as foreign legal consultants in their territory. These 26 jurisdictions account for approximately 85 percent of the total legal services market in the United States.
- c. Also in 2005, the Virginia Bar Association approved the proposed adoption of a foreign legal consultant system in Virginia, and that proposal is now awaiting approval by the Virginia Supreme Court.
- d. The Government of the United States has again conveyed to the ABA Japan's views on foreign legal consultant systems in the United States as described in its October 2004 requests and asked that those views be conveyed to the Conference of Chief Justices, the ABA GATS Task Force and the appropriate people at the ABA Center for Professional Responsibility.
- e. The Government of the United States will continue working with the ABA on these matters, and will inform the Government of Japan of any responses by state authorities to its requests.

2. Product Liability Law:

- a. President Bush has stated that legal reform is a cornerstone to a comprehensive economic expansion program. For this reason, this Administration is firmly committed to alleviating the undue burden on the

business community from inappropriate tort litigation and unreasonable awards, and has supported a number of bills to that end.

- b. President Bush strongly supports enactment of medical liability reform and asbestos litigation reform legislation to expedite resolutions and curb the costs of lawsuits. To that end, the President has expressed his commitment to continue to work with the Congress to pass meaningful legal reforms, starting with reform in these areas.
3. Class Actions: On February 18, 2005, the President signed into law the Class Action Fairness Act of 2005. This law makes reforms to the class-action system that will keep out-of-state businesses, workers and shareholders from being dragged before unfriendly local juries, or forced into unfair settlements, while maintaining the valuable benefits that class action lawsuits can have to efficiently allow injured parties to receive proper compensation. Specifically, the Act moves most large, interstate class actions into federal courts, preventing lawyers from shopping around for friendly local venues. And it provides new safeguards to ensure that plaintiffs and class-action lawsuits are treated fairly, including by requiring heightened judicial review of settlements. Enactment of this bill is a significant step in reforming class action litigation.

## 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. **Deregulation of Licensing and Reporting Requirements:** The Telecommunications Act of 1996 requires the FCC to review the rules issued under the Communications 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. Regarding certification and licensing criteria for foreign carriers' entry into the U.S. telecommunications market, the United States welcomes the Government of Japan's participation in biennial reviews and will seriously consider any recommendation on its merits.
- C. **Regulatory Predictability**
  1. Dichotomous Classification of Telecommunication Service and Information Service:
    - a. In the Notice of Proposed Rulemaking entitled In the Matter of IP-enabled services (WC Docket 04-36), released in March 2004, the FCC initiated a proceeding to examine opportunities that allow consumers greater choices created by voice services provided over the Internet and provide a measure

of regulatory stability to the communications marketplace and to further promote the development of these Internet-based services. The Notice recognized not only that Internet services should continue to be subject to minimal regulation, but also that mechanisms to implement important social objectives, such as public safety, emergency 911, law enforcement access, consumer protections and disability access, may change as communications migrate to Internet-enabled services. In this proceeding, FCC has asked for comment, on, *inter alia*:

- (1) The jurisdictional nature of IP-related services;
  - (2) Appropriate basis or bases for asserting Federal jurisdiction over the various categories of IP-enabled services;
  - (3) Whether, and on what grounds, one or more classes of IP-enabled services should be deemed subject to *exclusive* federal jurisdiction with regard to traditional common carrier regulation; and
  - (4) The proper legal classification and regulatory treatment of each specific class of IP-enabled services commenters have identified.
- b. The United States Government will continue to provide information on its review of the dichotomous framework of Information Service and Telecommunications Service.
- c. In June 2005 the United States Supreme Court ruled in the case *National Cable and Telecommunications Association v. Brand X Internet Services*, upholding the FCC decision classifying cable modem service as an information service. In August 2005, the Commission determined that wireline broadband Internet access services are defined as information services functionally integrated with a telecommunications component.
2. Development of UNE Regulations: The emergence of alternative platforms for delivering services (i.e., cable modem, broadband over powerline, and wireless broadband) has prompted the United States Government to reexamine how best to promote facilities-based competition. In 2004, a U.S. appeals court found that the market conditions under which unbundling could be imposed should be better defined. In February 2005 the FCC released new rules governing the provision of unbundled elements to competitive carriers. These revised rules impose unbundling obligations in a more targeted manner where requesting carriers have undertaken their own facilities-based investments and will be using unbundled network elements in conjunction with self-provisioned facilities. This approach is intended to spread the benefits of facilities-based competition to all consumers, particularly small- and medium-sized enterprise customers, consistent with technology trends that are reshaping the industry. The rules are designed to remove unbundling obligations over time as carriers deploy their own networks

and downstream local exchange markets exhibit the same robust competition that characterizes the long distance and wireless markets.

3. Universal Service: The Government of the United States and the Government of Japan reaffirmed their continued intention to maintain any universal service mechanism in line with WTO Reference Paper commitments.

**D. Harmonization of State Level Regulation**

1. 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.
2. Taking account of concerns raised by the Government of Japan in this area, the Government of the United States will provide the Government of Japan with relevant information on NARUC's work.

**E. Access Charges**

1. Inter-State Access Charges:
  - a. The FCC is currently in the process of reviewing recommendations and soliciting further comment for developing an intercarrier compensation regime. In March 2005, the FCC released a Further Notice of Proposed Rulemaking with the goal of replacing the myriad existing intercarrier compensation regimes with a unified regime designed for a market characterized by increasing competition and new technologies. In a preceding rulemaking, the Commission acknowledged a number of problems with the current intercarrier compensation regimes (access charges and reciprocal compensation) and expressed interest in identifying a unified approach to intercarrier compensation. The Commission solicited comment on a bill-and-keep approach to reciprocal compensation payments governed by section 251(b)(5) of the Act. The Commission also sought comment on alternative reform measures that would build upon the current requirements for cost-based intercarrier payments.
  - b. Several industry groups have developed proposals for comprehensive reform of existing intercarrier compensation regimes and submitted those proposals to the Commission. In this *Further Notice*, the FCC is soliciting comments on these proposals, (available at <http://www.fcc.gov/wcb/ppd/>) including the legal and economic bases for these proposals, as well as the end-user effects and universal service issues implicated by them. In addition to the comprehensive reform proposals submitted in the record, the FCC is seeking comment on alternative reform measures, including changes to the existing intercarrier compensation regimes and cost

standards. The FCC will continue to reform intercarrier compensation through transparent and fair procedures.

2. **Intra-State Interconnection Rates**: The Office of the U.S. Trade Representative will take reasonable steps to facilitate Government of Japan requests for information about TELRIC models used in specific states and about opportunities for participation in the development of such models.

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

1. The Government of the United States will continue its efforts to minimize delays and maximize transparency of procedures in export licensing and TAA approval for commercial communications satellites in accordance with U.S. laws, regulations, and policies. For example, the Government of the United States now provides more forms on the web and has increased the use of on-line applications to help ease the licensing process. The Government of the United States will respond to the extent possible to requests for information from the Government of Japan regarding improvements resulting from this new system.
2. The Government of the United States and the Government of Japan have conducted an informative dialogue on export licensing for commercial satellites. Recognizing the importance of U.S.-Japan relations, the Department of State is prepared to discuss specific issues with the Government of Japan if necessary.

**G. Promotion of Trade in Telecommunications Equipment**

1. Following several meetings, MIC and FCC reached a common view on respective procedures suitable for mutual recognition of telecommunications equipment and equipment subject to EMC (electro-magnetic compatibility) requirements. With regard to telecommunications equipment, the Governments of the United States and Japan expect to start formal negotiations in November 2005 with a view toward conclusion of those negotiations in early 2006, if feasible.
2. Regarding EMC, the Government of the United States confirmed that it is prepared to work with Japan 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.

- H. Network Channel Terminating Equipment (NCTE):** The Government of Japan will invite public comment regarding the proposed abolishment of the streamlined procedures of the 1990 Exchange of Letters on Network Channel Terminating Equipment (NCTE) (“the 1990 Letters”) which were described in the Third Report to the Leaders. Unless sufficient evidence demonstrating the continued need for these revised procedures are

submitted from the interested parties through public comments, the 1990 Letters will cease to be applied in and after FY2006.

### **III. INFORMATION TECHNOLOGY**

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

1. The Government of the United States recognizes the importance of ensuring the protection of the right of making available, rights concerning live performances, and moral rights, as well as the importance the Government of Japan places on the protection of unfixed works. The Government of the United States has also had a series of productive discussions with the Government of Japan concerning Government of Japan's requests for clear and reliable protection of these items under U.S. law, including the Copyright Act. The Governments of the United States and Japan will continue discussions on these issues.
2. To ensure adequate continuing protection, the Government of the United States will continue to monitor the development of case law concerning the protection of moral rights.
3. The Government of the United States will continue discussions with the Government of Japan on the protection of the right of rental for computer programs with special emphasis on video game programs.

**B. Adequate Protection of Rights under the Digital Millennium Copyright Act:** The Governments of the United States and Japan recognized the importance of striking an appropriate balance between the rights of copyright owners and the interests of ISPs and alleged infringers. In this connection, the Government of the United States will continue to observe future developments of case law in this area.

**C. New Copyright Issues Pertaining to the Wider Use of the Internet and the Development of Digital Technologies:** The Governments of the United States and Japan exchanged useful information about adequate legal protection and effective legal remedies against the circumvention of effective technological measures. The United States will review the affect of the provisions of the Digital Millennium Copyright Act related to the circumvention of access control technologies on non-infringing uses of any particular class of works and provide appropriate exceptions. This review commenced on October 3, 2005 with the first request for comments from the public. The two Governments will continue to discuss this matter.

#### **D. U.S.-Japan Cooperation to Improve Intellectual Property Rights Protection:**

1. To combat the serious and growing problem of the global trade in pirated and counterfeit goods, both the United States and Japan have recently established major new initiatives. In October 2004, the United States launched the Strategy



Targeting Organized Piracy (STOP!), and in June 2005, Japan launched the “Intellectual Property Strategic Program 2005.”

2. In addition to establishing their own initiatives in this area, the United States and Japan have been and will continue to closely cooperate on strengthening intellectual property rights protection and enforcement. Along with cooperating multilaterally, the two Governments, for example:
  - a. Held bilateral meetings in November 2004 and April 2005 to promote IPR protection and enforcement in Asia and around the world;
  - b. Co-sponsored the APEC Anti-Counterfeiting and Piracy Initiative, which was endorsed at the meeting of APEC Ministers Responsible for Trade in June 2005 in the Republic of Korea; and
  - c. Discussed under the Regulatory Reform Initiative ways to cooperate to combat piracy of digital content.
3. The Governments of the United States and Japan will continue to cooperate in bilateral, regional, and multilateral fora to promote greater protection for intellectual property rights world wide.

#### **IV. ENERGY**

The Government of the United States is taking measures to promote a comprehensive energy policy which will improve the functioning of the U.S. energy market. This process is welcomed by the Government of Japan.

##### **A. Federal Energy Regulatory Commission (FERC) Market Regulation Policies and Measures**

1. As reflected in its strategic plan, FERC’s goals are to secure high quality, environmentally responsible infrastructure through consistent policies; foster nationwide competitive energy markets as a substitute for traditional regulation; and protect customers and market participants through vigilant and fair oversight of both traditionally regulated and transitioning energy markets.
2. FERC’s open and transparent policy making procedures allow all interested parties the opportunity to participate in the process, thus supporting an investment environment that is responsive to market conditions. As part of its outreach, FERC regularly holds open conferences in which parties may address policy decisions. Proposed rules are issued through a formal Notice of Proposed Rulemaking (NOPR) process, where they are opened up to further public comment. Mandated by law, this process ensures that the general public, and not just those most affected by the proposed rule, will have ample opportunity to indicate any concerns about the provisions and requirements of the proposal.

Since FERC carefully takes into account the concerns of all those who comment, final rules approved by FERC may differ substantively from the rules as initially proposed. FERC currently has a number of ongoing rule makings in progress.

3. FERC remains committed to fostering nationwide competitive energy markets and continues its efforts to promote a more positive energy industry investment environment. In this regard, FERC has conducted a series of infrastructure conferences and technical workshops on investment in electric transmission infrastructure. On June 15, 2005, FERC took action on adoption of the Proposed Pricing Policy for Efficient Operation and Expansion of Transmission Grid.

## **B. Federal and State-Level Regulations**

1. While the United States' system of government provides for separate federal and state responsibility over energy regulation, FERC continues to take steps to make regulation of the wholesale energy markets more uniform across all states. FERC has issued a standardized large generator interconnection rule that makes more uniform the interconnection process and protocols for new generators that are contained in the open access transmission tariffs of all public utility transmission providers. The Final Rule was issued July 24, 2003, and a compliance directive to implement the Final Rule was issued December 20, 2004. A second Final Rule, for standardized small generator interconnections, was issued May 12, 2005. This second Final Rule adopted many of the best practices recommended by the states' National Association of Regulatory Utility Commissioners (NARUC). Also, a Notice of Proposed Rulemaking on wind generator interconnection protocols was issued January 24, 2005.
2. In addition, FERC has promoted the formation of Regional Transmission Organizations (RTOs) and Independent System Operators (ISOs) to improve efficiency in wholesale electricity markets and to ensure that electricity consumers pay the lowest price possible for reliable electricity service. On May 11, 2005, FERC issued a staff document and invited all interested persons to file comments addressing long-term transmission rights in electricity markets operated by RTOs and ISOs.

**C. Comprehensive Energy Legislation:** The Energy Policy Act of 2005, intended to modernize energy production and distribution systems, was signed by President Bush on August 8, 2005. The Act includes the following provisions:

1. More favorable tax treatment for expanding or modernizing the electricity grid and building natural gas pipelines;
2. Establishment of mandatory federal electricity grid reliability rules;
3. Clear final authority for FERC to approve liquefied natural gas (LNG) import terminals; and

4. Repeal of the Public Utility Holding Company Act.

D. **Review on Public Business:** The Government of the United States continues to assess the impact of Publicly Owned Entities (POEs) on competition in a liberalized market. FERC regularly consults with the American Public Power Association (APPA) and the National Rural Electric Cooperative Association (NRECA) on a host of market related issues. Many POEs have already made their transmission delivery service tariffs consistent with FERC's open access transmission policies. The Energy Policy Act of 2005 allows FERC to ensure open access among all transmitting utilities, including POEs. FERC actively encourages ISOs and RTOs to include POEs as members. Generally, municipalities that do not own generation rely on the opportunities to purchase their power at wholesale from competitive generation markets where all investors can participate.

E. **Price Cap Regulation in Wholesale Market:** FERC can impose price caps or bid caps on wholesale electricity when it deems that such steps are necessary and the only way to curb the abusive exercise of market power. As such, FERC uses this authority sparingly to not interfere with market participants making sound business decisions.

F. **Public Trust and Energy Markets**

1. FERC and the Commodity Futures Trading Commission (CFTC) actively monitor energy markets. In this regard, FERC strengthened its market monitoring capabilities by significantly increasing the size and experience its staff. Approximately 50 people were hired from the outside when FERC's new Office of Market Oversight and Investigation (OMOI) was established. OMOI is now staffed with about 100 personnel dedicated to monitoring and overseeing electricity and natural gas markets in the United States.

2. FERC also issued updated standards of conduct behavioral rules for public utility transmission providers and natural gas pipelines in 2004. In addition, FERC increased its auditing and investigations, and is aggressively pursuing violations. The results of FERC's investigations are released to the public.

3. FERC's Office of Market Oversight and Investigation enforces the regulations on "Accounting and Reporting of Financial Instruments, Comprehensive Income, Derivatives and Hedging Activities," issued in October 2002, and takes necessary action when appropriate.

V. **MEDICAL DEVICES AND PHARMACEUTICALS**

A. **FDA's Meetings with Foreign Industry:** MHLW has continuously offered meaningful opportunities for directly exchanging views with U.S. and other foreign medical device and pharmaceutical industries operating in Japan. FDA provides continuous and meaningful opportunities for discussions concerning its regulations on medical devices

and pharmaceuticals with Japanese and other foreign pharmaceutical and medical device companies who have submitted an application with FDA. On a similar basis, Japanese and other foreign industry associations are provided information on FDA's website, opportunities to participate in public meetings, and opportunities for direct meetings with FDA.

**B. Compliance with Guidelines of the International Conference on Harmonization (ICH)**

1. Based on the intention of the timely implementation of internationally harmonized guidelines, FDA and MHLW are discussing the incorporation of and compliance with such guidelines at meetings of ICH.
2. As has been discussed at ICH, FDA continues to fully support the use of MedDRA terminology in the international setting for which it was designed.
3. With regard to the test duration of chronic toxicity testing of new drugs in non-rodents, FDA would be willing to provide updated information about the number of cases requiring longer duration than that according to the ICH guideline in response to a request from MHLW through the ICH steering committee and to resolve this issue technically.

**C. Early Implementation of Matters Agreed Upon by the Global Harmonization Task Force (GHTF):** In recognition of the importance of the global convergence of regulatory systems, FDA is striving toward implementation of "Essential Principles of Safety & Performance of Medical Devices" and other matters that have not been fully implemented in the United States, and making efforts to deepen technical discussions with regulatory authorities of relevant countries under the framework of GHTF.

**D. Mutually Agreed Approach towards an MRA or a Similar Information Sharing Arrangement on Good Manufacturing Practices (GMP) of Medical Devices and Pharmaceuticals:** Since the revised Pharmaceutical Affairs Law that was put in force in April 2005 in Japan will require GMP certification for medical device and pharmaceutical approval, an MRA on GMP or establishment of a similar cooperative relationship will enable innovative medical devices and pharmaceuticals to be brought to market more quickly. With the goal of achieving GMP mutual recognition, or a similar information sharing cooperative arrangement, MHLW has urged FDA to advance GMP cooperation between the United States and Japan on medical devices and pharmaceuticals in a positive manner. FDA has indicated that it will not pursue an MRA but acknowledges that closer cooperation between FDA, MHLW and PMDA, such as the recently concluded confidentiality agreements among the three organizations, could lead to improved patients' access to medical devices and pharmaceuticals developed by U.S. and Japanese companies and that it will be beneficial for the relevant industries of both the United States and Japan. FDA and MHLW will continue to seek a mutually agreed approach to share certain defined information within the limits of their resources and legal ability to do so. As a means to pursue enhanced cooperation, FDA has given

MHLW access to the FACTS database, a computerized inventory of regulated firms, which contains the results of inspections of medical device and pharmaceutical manufacturers, and will provide clarification of entries when MHLW requests such information. FDA and MHLW will continue to discuss procedures for sharing medical device information and GMP inspection reports on pharmaceuticals. For GMP of pharmaceuticals, FDA and MHLW have already exchanged letters related to an MOU and agreed that both FDA and MHLW will provide copies of inspection reports. In contrast, however, such a partnership has not yet been formed in the field of medical devices. As a first step, FDA has shown its intention, on a case by case basis, to respond when MHLW and PMDA request information on QMS auditing. This topic will be discussed by MHLW and FDA in developing the framework associated with the confidentiality agreement. With an aim to facilitate cooperation in the auditing of medical devices between both governments, MHLW and FDA will seek further concrete steps to be included in the framework.

- E. **Mutually Agreed Approach towards an MRA or a Similar Information Sharing Arrangement on Good Clinical Practices (GCP):** In view of Japan's growing accumulation of experiences following the introduction of ICH Good Clinical Practice standards, FDA is willing to provide training to personnel of MHLW and PMDA in order to promote the exchange of information on GCP between Japan and the United States within its resource constraints. MHLW, PMDA and FDA will discuss this matter and design a mutually agreed approach.
- F. **Simplification of Data Requirements for Investigational New Drugs (IND) Applications:** FDA is willing to discuss at ICH what data on manufacturing and control should be required in the investigational stage for new drug applications, and to study specifically how to implement the simplification of IND applications under the framework of discussions between FDA and MHLW.

## VI. FINANCIAL SERVICES

- A. **Registration Requirements for Foreign Issuers in Case of Mergers, Consolidation, or Reclassification of Securities**
  - 1. In 1999, the U.S. Securities and Exchange Commission (SEC) adopted a rule that exempts from registration requirements offers where the acquiring company and the target company are foreign companies, and where U.S. residents hold less than 10 percent of the shares of the target company. SEC staff recognizes the Japanese Government's view that this rule has extra-territorial effects. SEC staff is aware of Japan's interest in raising this level. However, at the time of adopting this rule, the SEC carefully considered the level of U.S. ownership that was desirable and appropriate for purposes of this exemption and in the interest of investor protection.
  - 2. In addition, even above the 10-percent level of U.S. ownership, more tailored relief has been adopted for foreign companies that addresses conflicting

regulatory mandates and offering practices. Accordingly, Japanese companies engaged in merger and acquisition or other transactions that fail to meet the 10-percent threshold are encouraged to raise specific concerns with SEC staff.

- B. **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. Reliance on government support to meet capital requirements is one of several factors that may be taken into account in determining comparability of capital. No one factor is determinative. More than 30 foreign banks are FHCs. The Government of the United States welcomes applications for FHC status by any foreign financial institutions that meet these prudential criteria.
- C. **Regulation on Sales and Offers of Foreign Investment Trusts/Companies:** 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 has also required non-Canadian foreign investment companies seeking 7(d) orders to comply with the rule's conditions. 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)). The SEC staff remains willing to consider applications for 7(d) orders from any foreign investment company, including those organized in Japan. Moreover, additional avenues for access to the U.S. market for asset management services exist. Indeed, SEC staff interpretations and innovations in the mutual fund industry have significantly increased the ability of foreign advisers, which can easily register with the SEC, to offer their services to U.S. investors and to establish funds that are organized in the United States.
- D. **Participation of US Investors to Foreign Exchange Traded Funds (ETFs):** Because ETFs operate differently from traditional investment companies, U.S. ETFs have had to seek exemptive relief from certain provisions of the Company Act. In some cases, in providing exemptive relief to U.S. ETFs, the SEC has provided relief from the prospectus delivery requirements of Section 24 of the Company Act, thereby allowing sales of shares to purchasers in the secondary market unaccompanied by a prospectus. (See In the

Matter of iShares Inc. and iShares Trust, Investment Company Act Release No. 25623 (June 25, 2002)). Like U.S. ETFs, non-U.S. ETFs likely would also have to seek exemptive relief, in addition to a 7(d) order, to register under the Company Act. Moreover, like U.S. ETFs, non-U.S. ETFs could seek, as part of their applications for exemptive relief, relief from the requirements of Section 24 of the Company Act.