

Annual Reform Recommendations from the
Government of the United States to the Government of Japan under the
U.S.-Japan Regulatory Reform and Competition Policy Initiative

October 15, 2008

The U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) remains an important vehicle for promoting reforms that help spur economic growth as well as for further deepening the economic and trade relationship between the United States and Japan. In this respect, the United States looks to Japan to continue to pursue a path of meaningful, growth-oriented reform.

The United States' recommendations to Japan in this eighth year of the Regulatory Reform Initiative outline areas where new progress can be made that would, for example, help further remove or streamline unnecessarily burdensome barriers to trade and economic activity, improve the business environment such as by enhancing the transparency of regulatory processes, and stimulate new business opportunity through enhanced competition and through the opening of new markets to better serve consumer needs.

The United States has proposed a broad array of recommendations for Japan take new measures, consistent with the above-mentioned objectives, in the areas of communications, information technologies, intellectual property, medical devices and pharmaceuticals, competition policy, commercial law and legal systems, transparency, privatization of government corporations, distribution, and agriculture, among others.

Recommendations submitted by both the United States and Japan are discussed over a period of several months in four Working Groups covering telecommunications, information technologies, medical devices and pharmaceuticals, and cross-sectoral issues, as well as separately at a senior level in the High-Level Officials Group. Progress achieved as a result of this work is then reflected in the Initiative's annual Report to the Leaders.

The Government of the United States continues to look forward to constructive discussions on its recommendations and also welcomes receiving recommendations from the Government of Japan.

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RECOMMENDATION HIGHLIGHTS

COMMUNICATIONS

The United States continues to monitor Japan's regulatory reform efforts in the telecom sector in response to evolving technologies and the growing convergence between telecommunications and broadcasting services. The United States believes that increased competition and a less prescriptive approach to technology would foster innovation and offer Japanese consumers greater choice at lower prices. Related to these broad goals, ongoing issues of interest include the Government of Japan's preparations for a decision on the reorganization of the dominant carrier Nippon Telegraph and Telephone (NTT) and plans for drafting a new law to cover converged services. The United States urges Japan to continue taking steps to ensure a competitive environment characterized by transparent development of regulation for the benefit of new entrants, competitive carriers, and equipment manufacturers.

RECOMMENDATION HIGHLIGHTS

Ensuring Market-Based Technology Decisions:

Improve transparency and increase stakeholder participation in policymaking and regulations; promote efficient use of spectrum to increase opportunities for new services and technologies; foster a technology-neutral licensing regime where service providers can introduce innovative technologies.

Strengthening Competitive Safeguards on Dominant Carriers: Prevent anticompetitive behavior by carriers with market dominance as telecom services move to IP-based networks;

ensure a competitive playing field for both wireline and mobile interconnection; promote facilities-based competition across different broadband platforms.

Developing a Regulatory Framework for Converged and Internet-enabled Services:

Ensure that any new regulatory framework is developed in a transparent manner and minimizes burdens on operators while promoting new entry and competitive opportunities.

INFORMATION TECHNOLOGIES

The United States' recommendations seek to promote competition and confidence in government procurement of information technologies (IT), enhance the use of IT in Japan's financial and healthcare sectors, promote the strengthening of intellectual property rights (IPR) enforcement and protections, and ensure any revisions in the implementation of the Privacy Act also enhance the business environment.

RECOMMENDATION HIGHLIGHTS

Health IT: Provide incentives for the use of innovative information-sharing technologies; promote technology neutrality and interoperability; promote harmonization with international standards.

IT-Related Financial Reform: Facilitate alternative non-bank payment services in the area of electronic payments; ensure communication and collaboration between relevant ministries and private sector.

IPR Protection and Enforcement: Promote innovation and economic growth by strengthening copyright enforcement, harmonizing approaches with international best practices, and streamlining patent procedures.

IPR Cooperation: Continue to cooperate bilaterally and through multilateral fora to promote strong IPR protection and enforcement with a focus on the Asia-Pacific region.

Government IT Procurement: Allow contractors to own the intellectual property rights to software they develop; limit vendor liability; prohibit backdating of contracts; expand use of competitive bidding rules; improve transparency.

Privacy: Ensure that any revisions of Privacy Act implementation enhance consistency and predictability, and do not restrict trans-border data flows.

MEDICAL DEVICES AND PHARMACEUTICALS

The United States encourages Japan to reform its reimbursement pricing and regulatory systems for medical devices and pharmaceuticals to foster industry's ability to develop innovative products and to improve the access of patients to such products. Japan's 2007-2008 "Vision" policy papers called for eliminating the drug and device lags, developing an internationally competitive industry, and making Japan an attractive investment destination. The United States supports Japan's goal to end the device and drug lags by using an expected increase in reviewers to expedite product approvals and by reforming the pricing system to improve incentives for research and development of advanced medical products.

RECOMMENDATION HIGHLIGHTS

Pricing Reform: Stimulate research, development and marketing of advanced medical devices and drugs by rewarding innovation; improve understanding of pricing issues by increasing industry-government communication.

Regulatory Reform: Reduce device approval times by attaining performance goals and hiring more reviewers; cut drug approval times by reforming the review and clinical-trial consultation systems; foster simultaneous global drug development; expedite approvals of minor changes in devices.

Blood Products: Implement a pricing system based on the characteristics of the plasma product industry;

reform labeling rules; remove import restrictions; expedite approvals of minor changes in products.

Nutritional Supplements: Develop a new regulatory category that would allow for ingredient-specific health claims; improve transparency during the development of health food safety regulations; improve processing time for new and revised food additive applications.

Cosmetics / Quasi-Drugs: Streamline the quasi-drug approval process; allow additional claims for cosmetics that are within the existing scope of currently approved claims; streamline import processes.

FINANCIAL SERVICES

The United States welcomes Japan's Better Markets Initiative and its efforts to enhance the global competitiveness of Japan's financial markets and regulation. Robust financial and capital markets are essential for sustained economic growth, efficient capital allocation, job creation, and innovation. In addition to specific measures that would improve market efficiency and afford more options to Japanese savers, investors and workers, the United States requests that Japan continue its recent progress on regulatory reform in the financial services sector notably by taking action in the following areas.

RECOMMENDATION HIGHLIGHTS

Defined Contribution Pensions: Improve the national defined contribution pension system by increasing contribution limits, allowing employee contributions, allowing early access to funds in special circumstances, allowing investment advice service to all participants, and by introducing a defined contribution pension scheme for public service employees.

Transparency: Expand the body of published written interpretations of financial laws, including by active use of no-action and interpretive letters; ensure all stakeholders to provide input on draft laws

and regulations; further the transparency and predictability of rule interpretation and inspection processes.

Credit Bureaus: Promote sound credit underwriting, deter excessive lending and improve consumer welfare and competitive credit markets by creating a legal and regulatory framework for a credit bureau system that facilitates more accurate risk pricing for consumers and small businesses by collecting and providing fair, open access to comprehensive full-file credit information.

COMPETITION POLICY

The deterrence of anticompetitive conduct that clearly harms consumers will contribute to a stronger and more efficient business sector and benefit Japanese consumers and the Japanese economy as a whole. While vigorous enforcement by the Japan Fair Trade Commission (JFTC) is crucial to achieve that goal, care must be taken to ensure that Antimonopoly Act (AMA) enforcement policy does not chill procompetitive conduct and that the public and the business community have faith that JFTC investigations are fair and impartial. At the same time, bid rigging remains a continuing problem, and bold measures are needed to address this matter effectively, including by preventing government officials from assisting in bid rigging activities. The United States urges Japan to take measures to improve further Japan's competition environment.

RECOMMENDATION HIGHLIGHTS

Improving Antimonopoly Compliance and Deterrence: Strengthen measures against cartels; avoid surcharges on unilateral conduct; review AMA exemptions on international aviation; improve pre-merger notification procedures; strengthen JFTC economic analytic capabilities.

Improving Fairness and Transparency of JFTC Procedures: Eliminate or fix the post-order hearing process to ensure procedural fairness; improve the

fairness of AMA investigations and establish a mechanism to resolve procedural fairness complaints; introduce procedures for protecting attorney/client confidential communications.

Addressing Bid Rigging: Prevent government-assisted bid rigging and address conflicts of interest by government officials in procurement; expand administrative leniency programs; improve procurement practices of local governments.

COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

The United States recommends that Japan take bold steps to encourage cross-border merger activities in Japan and to improve its commercial law system so that it promotes efficient business practices and management accountability to shareholders in accordance with best international practices. Japan should also ensure that it establishes a legal climate conducive to the efficient provision of international legal services, including through alternative dispute resolution mechanisms, to all parties in Japan that need such services. In today's high technology era, where innovation drives dynamic global competition and innovation incentives are dependent on the ability of innovators to prevent others from appropriating their technological breakthroughs, it is also important that the legal system provide mechanisms to punish trade secret thieves without having to publicly disclose those very same trade secrets. The United States urges Japan to take measures to further improve Japan's commercial and legal environments.

RECOMMENDATION HIGHLIGHTS

Promoting Cross-Border M&A: Reform Japan's legal system to encourage more cross-border M&A; adopt reasonable tax-deferral rules for such M&A transactions; protect shareholder interests when adopting anti-takeover measures; adopt simple procedures enabling a foreign company to convert into a Japanese corporation.

Strengthening Good Corporate Governance: Ensure the independence of outside directors; encourage stock exchange rules enhancing the corporate governance of listed companies; ensure sufficient protection of minority shareholders; encourage active proxy voting and disclose the full

results of proxy votes.

Achieving Legal System Reform: Permit foreign lawyers (*gaiben*) to form professional corporations, allow all law firms to establish branches throughout Japan; allow Japanese lawyers to associate with international legal partnerships; simplify minimum qualification criteria and speed-up approvals of new *gaiben* applications; permit *gaiben* to represent parties in all international arbitration proceedings; facilitate criminal prosecution of trade secret theft.

TRANSPARENCY

Transparent, predictable regulatory and related processes remain fundamental to any positive business environment. While some welcome improvements have been made in Japan in recent years, actual conditions faced by businesses indicate that such improvements have not been made uniformly across the Japanese Government. New measures are also necessary by Japan to further improve its business environment and establish high standards of transparency – including new approaches to improve transparency of Japan’s government-commissioned advisory councils and related groups, and new steps to ensure that those parties that must comply with regulations and agency interpretations of regulations have the necessary information to do so fully. In turn, stronger transparency in Japan’s regulatory processes can also help better ensure that consumer protection and welfare is most effectively served.

RECOMMENDATION HIGHLIGHTS

Improve Access to Advisory Groups: Implement new rules to better ensure transparency of and access for the public and stakeholders to provide input into government-appointed advisory groups; develop and promote transparency best practices for such groups on a government-wide basis.

Strengthen Public Comment Procedures: Lengthen the public comment period; ensure agencies give public comments ample consideration; seek views from the public on the effectiveness of the public comment system and allow opportunities to suggest improvements.

Ensure Transparency of Interpretations of Regulations: Ensure Ministries and Agencies make public in writing any statements of policy or generally applicable interpretations regarding their regulations.

Promote Transparency in Re-organization of Government Functions: Ensure transparency is secured in any re-organization of government functions relating to consumer protection in order to enhance predictability and clarity as well as to secure effective consumer protection.

OTHER GOVERNMENT PRACTICES

The United States recommends that Japan adopt new reform measures across a variety of areas to help increase convenience and remove unnecessary costs, ensure consumer protection, and promote the growth and development of a more attractive business environment. In the area of agriculture, steps are recommended to facilitate smooth trade in agricultural products, including by increasing the transparency and predictability of Japan’s import regime for growers while ensuring Japan’s compliance with science and its obligations under the WTO SPS Agreement for delivering safe agriculture and food products to Japanese consumers. The United States also recommends steps to further improve Japan’s insurance market that also increase consumer protection and choice; help reduce the time and cost needed to construct and operate wind power projects; and improve the business environment for foreign nationals through streamlined consular requirements.

RECOMMENDATION HIGHLIGHTS

Agriculture Practices: Ensure regulatory compliance with CODEX standards for organic crop imports, safe food additives, and testing regimes for pre- and post-harvest pesticides; implement effective import measures for maximum residue levels that are the least trade restrictive possible.

Wind Energy: Consolidate regulatory processes for construction and operation of wind power projects.

Insurance Cooperatives: Require that insurance cooperatives (*kyosai*) meet the same obligations as private insurers to level the playing field between them and bolster consumer protection.

Insurance Issues: Take steps to facilitate new opportunities for independent insurance agents; ensure the effectiveness of the bank sales channel.

Consular Issues: Revise re-entry permit rules to minimize burdens on visa holders in Japan

PRIVATIZATION

Japan's privatization and reform of Japan Post continues to command strong interest by the United States as a process that holds many potential benefits for Japan's economy if it is undertaken in a fully market-oriented manner. The United States also deems it important that these reforms are undertaken transparently and bring about a level playing field between Japan Post companies and private sector competitors in Japan's banking, insurance, and express delivery markets, and thus continues to urge Japan to take all necessary steps to ensure equivalent conditions of competition are achieved.

RECOMMENDATION HIGHLIGHTS

Level Playing Field - Savings and Insurance:

Ensure the new postal financial institutions meet the same tax, legal, and regulatory obligations and are subject to the same supervisory standards as private firms; apply regulation to Japan Post financial institutions on a national treatment basis with other market participants.

Level Playing Field - Express Delivery: Apply equivalent customs clearance procedures for items handled by Japan Post Service as applied to private express carriers for similar actions, including applying the "duty declaration" system to EMS items; make business disclosures to demonstrate that cross-subsidization is not occurring between competitive and non-competitive services.

Competitive Conditions and New Products:

Create a level playing field in Japan's banking and insurance sectors before postal financial institutions are permitted to underwrite new or altered insurance products, and originate new lending services and other financial products by Japan Post.

Transparency: Ensure strong transparency in the implementation of Japan Post reforms, including providing interested parties meaningful opportunities for input and exchanges of views as the process proceeds; ensure the triennial review of Japan Post privatization is open and addresses the equivalence of competition in the banking, insurance, and express delivery sectors.

DISTRIBUTION

Promoting productivity, efficiency and transparency in Japan's distribution system is crucial to support Japan's economic growth and improve Japan's business environment. In this regard, the United States welcomes recent efforts made by Japan to streamline customs procedures. The United States requests that Japan take additional measures that will help lower distribution costs, improve transparency, and further streamline customs procedures for all industries.

RECOMMENDATION HIGHLIGHTS

Airport Landing and User Fees: Continue to reduce landing and user fees and promote transparency in the development of these fees.

De minimis: At least double the Customs Law's *de minimis* level to improve efficiency of customs procedures.

Customs Procedures: Take new streamlining steps that help promote more efficient import/export processing, including allowing postmortem declaration of exports and more flexibility for express carriers to select the customs office for customs declarations.

ANNEX

COMMUNICATIONS

- I. Ensuring Fair Market Opportunities for Emerging Technologies.** Consumer and operator choice in Japan’s telecommunications market continues to be constrained by an institutional structure where the Ministry of Internal Affairs and Communications (MIC) acts as regulator and industrial policy promoter for this sector. Absent moving regulatory functions to a fully independent governmental organization and divesting government ownership in specific operators, MIC could benefit from additional procedural safeguards to ensure impartiality through steps to improve transparency, promote more efficient use of spectrum, and institute technology-neutral principles.
- A. To foster greater transparency and objectivity in policymaking and revision of telecom regulations, the United States urges Japan to:
1. Open the selection process for participation in MIC-sponsored study groups, to prevent discrimination against any interested stakeholders (foreign or domestic), and ensure that participation in study groups is based on objective and transparent criteria;
 2. Ensure that financial or commercial interests of members of study groups which might benefit from specific recommendations are adequately identified;
 3. Ensure that any stakeholder with an interest in a subject matter addressed by a study group tasked with making recommendations to the MIC has an opportunity to provide proposed solutions and recommendations regarding the issue(s) under study;
 4. Ensure that proposals made to study groups are all given due consideration based on their merits, and that no proposal is given preference due to affiliation with any study group member or based on governmental interest in the entity making the proposal; and
 5. Ensure that, where study groups implement testing of new technologies, no entity is given unduly preferential treatment in the participation in such tests (e.g., through access to spectrum, test facilities, etc.).
- B. To enhance the ability of MIC to adapt more responsively to new technologies and services:
1. Analyze and provide public accounting of incumbents’ unused spectrum, or spectrum using outdated technology (e.g., Personal Digital Cellular) to determine criteria to identify “warehousing” (hoarding), and take steps to eliminate it;
 2. Develop open and transparent procedures to enable any interested party to formally petition MIC for the development, adoption, change, or deletion of

rules, and for MIC to act on a petition without requiring study group involvement;

3. Where MIC or any MIC-affiliated body is involved in any standardization effort (e.g., 4G) that identifies specific technologies, ensure that such process is subject to full and open notice and comment process, particularly where MIC will be advocating internationally for any such standard in fora such as the ITU;
4. Reconsider the feasibility of introducing auctions for particular spectrum bands, even only on a limited basis, to make it unnecessary for regulators to evaluate applicants on the basis of specific technologies; and
5. Consider revising service rules for specific spectrum bands to permit operators to use new technologies, subject to interference constraints, without new licensing – including use of video transmission services, such as mobile TV in bands originally designated for voice or data services (e.g., 700 and 800 MHz bands), or Time Division Duplex (TDD) technologies for use in bands designated as Frequency Division Duplex (FDD).

C. With respect to Next Generation Networks (NGNs):

1. Ensure any network requirements established by NTT involving interfaces necessary for interconnection with the NTT East or West networks are developed in an open and transparent fashion with all interested parties able to fully participate in the process (i.e., not discriminating against companies which have not been selected to participate in NTT-sponsored co-development programs);
2. Ensure that any new design by NTT East or West to deploy NGNs minimizes proprietary solutions that require interconnecting companies to invest in supplemental equipment; and
3. Ensure that NTT East and West publish plans in sufficient detail and give adequate advanced notice of proposed network changes to allow competing carriers ample time to introduce any necessary modifications into their own network.

II. Strengthening Competitive Safeguards on Dominant Carriers. MIC is beginning to develop policies and procedures to again consider fundamental change in the structure of NTT and its various affiliates. The United States urges Japan to ensure that decisions coming from this process adequately address means to safeguard competitive opportunities for new market entrants and equipment manufacturers and that the process is conducted in an open, unbiased manner without undue influence from NTT itself.

- A. Wireline Interconnection. Considering that application of the current Long-Run Incremental Cost (LRIC) model will expire at the end of FY2008, and to ensure a

competitive playing field under changing market conditions:

1. Re-evaluate whether the LRIC model has adequately brought interconnection rates in Japan down to internationally comparable levels;
2. Require NTT East and West to each set a cost-oriented interconnection rate, consistent with Japan's WTO obligations, taking into account differing costs of the respective regions; and
3. Eliminate the use of interconnection revenue as a source of cross-subsidization between NTT East and West.

B. Mobile Interconnection. For calls terminating on mobile networks:

1. Initiate a study, for timely publication, to determine whether mobile wireless termination rates are set at levels that reflect the principle of cost-orientation under efficient management, consistent with Japanese law; and
2. Analyze NTT DoCoMo's dominant position in the mobile sector, and the degree to which any existing mobile carriers exert market power in the sub market for call termination.

III. Developing a Regulatory Framework for Converged and Internet-enabled Services.

Rapid advances in technology allow consumers to access content in new ways (e.g. IPTV). Japan's regulatory approach needs to be flexible enough to allow innovation but also ensure that dominant players do not distort competition in this market. It is essential to develop any new rules for converged services in a transparent and non-discriminatory manner. Specifically, the United States recommends that Japan:

- A Provide an open and transparent procedure for assessing the need for new rules for convergent services (e.g., IPTV), and analyzing whether broadcasters unduly constrain competition; and
- B. With respect to consumer access to the Internet, clarify the authority and intent of MIC to ensure that ISPs and telecommunications carriers do not arbitrarily discriminate against users on the basis of usage of specific protocols, including peer-to-peer protocols, and review industry codes of conduct governing such matters.

IV. Advancing International Cooperation. Develop a basis for cooperating with like-minded WTO members to address trade policy implications of Members imposing surcharges on international communications in the name of capturing "network externalities."

V. Other. Continue to strengthen procedures and conditions for ensuring the impartiality of regulatory decision-making.

INFORMATION TECHNOLOGIES

- I. **Health Information Technology.** The United States encourages Japan to promote adoption of IT that improves the quality and efficiency of healthcare by:
 - A. Implementing the Grand Design action plan for health IT in a way that is transparent and promotes technology neutrality and interoperability.
 - B. Developing comprehensive reimbursement systems that reward use of innovative information-sharing technologies such as digital archiving, electronic medical records, and embedded and remote (telemedicine) technologies.
 - C. Promoting projects that provide opportunities to test and standardize innovative health IT in an open and interoperable manner.
 - D. Continuing to encourage a wide range of qualified IT vendors to participate in government-sponsored projects used to develop or showcase health IT systems.
 - E. Encouraging open dialogue between industry and government on the benefits of health IT and providing meaningful opportunities for interested parties, including international industry groups such as the American Chamber of Commerce in Japan, to present their views on health IT proposals, policies and regulations.
 - F. Promoting harmonization with international standards for health records and electronic medical records, such as Health Level 7 and Digital Imaging and Communications in Medicine, and ensuring that standards are well tested and validated to foster open and practical interoperability.

- II. **IT-Related Financial Reform.** The Financial Services Agency (FSA), and its Program for Further Financial Reform, has emphasized the importance of Internet transactions; the desire for the strategic use of IT to create a vibrant and competitive financial services sector in Japan; the importance of international openness, compatibility, and perspective; and the goal of diverse financial products and services for Japanese consumers to deliver superior customer choice, convenience and competitive costs. To achieve these goals:
 - A. Modify or enact regulations to allow for alternative non-bank payment service providers in the area of online, mobile and electronic payments.
 - B. Reaffirm the private sector's central role in expanding the use of IT in financial transactions. Ensure that the government works closely with the private sector when developing legislation or regulation related to e-banking, electronic fund settlements and payments, online financial transactions, or other online-related financial activity by providing meaningful opportunities for input from all interested parties, including technology providers.

- C. Ensure that any such legislation or regulation is compatible with international practice, to facilitate and promote both domestic and cross-border online financial transactions.
- D. Ensure that the FSA works closely with the IT Strategic Headquarters (ITSH) and relevant government agencies so that IT-related financial reforms are consistent with Japan's other IT and e-commerce regulations and policies, to provide predictability to the private sector.

III. Government IT Procurement Reform. The United States urges Japan to stimulate competition and increase fairness and transparency in government IT procurement by:

- A. Increasing Transparency. Increase transparency in IT procurement by taking these steps:
 - 1. Ensure compliance with the Basic Policy for the Public Procurement of Computer Systems (Basic Policy). Publish by November 2008 a report measuring compliance with and implementation of the Basic Policy. Use the Cabinet Secretariat's annual follow-up surveys on Basic Policy implementation as a resource to prepare the report.
 - 2. By March 2009, require agencies to provide to the Japanese Government's online database, for each IT procurement, such information as the bid announcements and procurement plans and specifications within one week of their release. Make this data public on a Japanese Government website and update the database every week.
 - 3. Ensure fair, transparent, and non-discriminatory competition for all major IT procurements by forming evaluation committees that include a broad range of experts to encourage and ensure objective evaluation.
- B. Expanding Japan's Buy-Dole System. Allow contractors to own intellectual property rights to software they develop through government-sponsored programs by requiring all agencies to implement by 2009 the April 2007 amendment to the Industrial Technology Enhancement Act. Require all agencies to use the relevant provisions of the model contract published by the Ministry of Economy, Trade and Industry to clarify the rights and obligations of vendors and agencies.
- C. Limiting Vendor Liability. Allow IT vendors to limit their liability to a level proportionate to the risks they take in government procurement transactions by:
 - 1. Implementing the Basic Policy's requirement that defines and circumscribes the liability of vendors in government IT procurement contracts.
 - 2. Requiring agencies to use the relevant provisions of the model contract published by the Ministry of Internal Affairs and Communications (MIC) to address liability issues in IT procurement contracts.

- D. Banning Backdating. Enforce the Basic Policy’s prohibition of contract backdating and its requirement that contracts should be swiftly concluded after winning bidders are chosen. Inform the public that complaints about backdating can be referred to a designated MIC office, and encourage that office to forward complaints to relevant agencies.
- E. Expanding Use of Competitive-Bidding Rules. Apply competitive-bidding rules that apply to the central government to independent administrative legal entities and government-sponsored private companies.
- F. Clarifying Contract Agreements. Clarify contract agreements by incorporating both procurement specifications and awardee proposals in final contract agreements.
- G. Employing “Best-Value” Principles. Enhance the benefits of services procured by the government by using “best-value” rather than “technically acceptable, lowest price” techniques to select IT contractors.

IV. Privacy. Based on the June 2007 “Summary of Opinions on the Protection of Personal Information” (Summary), the Quality-of-Life Policy Council (Council) has been reviewing the effectiveness of the Act on the Protection of Personal Information (Privacy Act). Following the Council’s recommendation that Japan should take necessary measures to standardize various implementation guidelines, the Cabinet Office began discussions in April 2008 to promote the integration and consistency of guidelines throughout government. The United States recommends that Japan:

- A. Develop clear, consistent, and predictable privacy guidelines across ministries, modified only when necessary to conform to the characteristics of individual business sectors.
- B. Ensure efficient cross-border data flows.
- C. Continue its educational campaign to prevent overreactions to the Privacy Act.

V. IT and e-Commerce Policymaking. To promote the use of information technology and electronic commerce throughout Japan’s economy, and to ensure international compatibility, the United States encourages Japan to ensure that its regulation of IT and e-commerce is transparent and flexible by:

- A. Considering Private Sector Input. Seek and consider private sector input at all stages of policy making from initial deliberations to implementation and facilitate private sector participation in all government-commissioned IT and e-commerce advisory bodies. Provide public comment periods of at least four weeks.
- B. Promoting Technology Neutrality. Ensure development of standards that promote technology neutrality. Implement laws, rules, and guidelines that promote competitive market conditions and give providers and users flexibility to choose

technologies that best suit their needs.

- C. Improving Implementation of Rulemaking. Enforce reasonable periods between the publication of final versions of IT and e-commerce regulations and their effective dates by providing the implementation dates well in advance so that interested parties can prepare for the change.

VI. Strengthening the Protection and Enforcement of Intellectual Property Rights. In the mutual interest of our countries to further promote innovation and economic growth through the strengthening of our intellectual property rights (IPRs) regimes, the United States urges Japan to adopt the following recommendations.

- A. Strengthen Enforcement Against Copyright Infringement. Promote the continued development and management of intellectual property content by:
1. Clarifying that the private use exceptions in Japan's Copyright Law does not apply to the downloading of content from unlawful sources;
 2. Updating laws and regulations to provide more effective "notice and takedown" systems for the removal of infringing content, including policies to identify infringers and hold them accountable, as well as other measures to enhance enforcement against infringement online; and
 3. Continuing to consider ex officio authority as a tool that will provide police and prosecutors broader authority to investigate and prosecute copyright crimes on their own initiative by removing the requirement of right holder consent for prosecutions.
- B. Statutory Modernization. Harmonize Japan's copyright regime with international best practices to address accelerating technological innovation and convergence, as well as increasing infringement by:
1. Providing a full range of civil and criminal remedies against circumvention of access controls and trafficking in tools for the circumvention both of access controls and of copy controls used by rights holders;
 2. Bringing Japan's terms of copyright protection (including for phonogram producers and performers) into line with global trends, including those of its OECD counterparts and major trade partners; and
 3. Ensuring the availability of deterrent remedies against infringement by adopting a system of pre-set statutory damages.
- C. Proposed Limitations or Exceptions to Copyright Protections and Other Copyright Related Recommendations. Ensure meaningful and timely opportunities for domestic and foreign rights holders to contribute and participate in deliberations on new limitations, exceptions, or the expansion of existing exceptions to copyright

protections and other copyright related recommendations by committees involved in drafting copyright related recommendations, including committees within the Agency for Cultural Affairs. Issues of note include, but are not limited to, decompilation of computer programs; infringement liability of search engines; and exceptions that impact scientific, technical, and medical or educational publishers.

D. Patent Procedures. Streamline patent procedures through promotion of work share efficiencies by:

1. *Deferred Examination System*. Provide for a system that ensures patent rights are clearly defined for third parties early in the application process, including reconsidering usage of the three-year deferred examination system.
2. *Patent Application Prosecution*. Implement procedures to identify all appropriate grounds of refusal at the earliest stage in the examination process, including grounds specific to dependent claims.
3. *Grace Period*. Implement legislation to ensure a full 12-month grace period for all invention disclosures by or derived from the inventor(s).

E. Transparency Regarding Other Initiatives. Maintain transparency on initiatives affecting the application of copyright, including in the digital environment, by (1) utilizing existing fora such as the Information Technologies Working Group to exchange information between governments on such initiatives; and (2) provide meaningful and timely opportunities for domestic and foreign rights holders to contribute to deliberations by relevant government entities including, but not limited to the Intellectual Property Strategic Headquarters, the Ministry of Internal Affairs and Communications, and the Agency for Cultural Affairs.

VII. Strengthening U.S.-Japan Cooperation on IPR Protection and Enforcement. Promote further cooperation between the United States and Japan to ensure adequate protection and enforcement of IPR domestically and around the world with a focus on the Asia-Pacific region.

MEDICAL DEVICES AND PHARMACEUTICALS

- I. **Input in Healthcare System Changes.** The United States encourages the Government of Japan and its advisory bodies to consult with U.S. industry on proposed reforms to its healthcare system and fully consider input at all levels and at the earliest possible time from U.S. industry before implementing any changes.

- II. **Medical Device and Pharmaceutical Pricing Reform and Related Issues.** The United States urges Japan to implement reimbursement pricing policies that improve the access of patients to innovative medical devices and drugs by taking the following actions:
 - A. Pharmaceuticals.
 1. Follow up on and systematically implement proposals and action items discussed by the Government-Private Sector Dialogue for Innovative Drug Discovery.
 2. Appoint a representative from U.S. industry to *Chuikyo's* Drug Pricing Expert Subcommittee.
 3. Reform the reimbursement pricing system by ensuring that initial prices of drugs reflect their level of innovation and maintaining prices of existing drugs during the patent or data exclusivity period while promoting generics.
 4. Foster the introduction of new and innovative drugs by refraining from implementing annual price revisions, which undermine the value of advanced medicines.
 5. Eliminate re-pricing based on market expansion and new indications to increase incentives for research on additional indications and to improve access to treatments.
 6. Encourage development of innovative medicines by refraining from using the Foreign Price Adjustment rule to impose downward price adjustments in cases where upward adjustments cannot be made.
 7. Apply innovation and marketability premiums across the full range of premiums, from the minimum to the maximum limits.
 8. Increase the prescription period for new drugs to 30 days and end the 30-day limit after a drug is on the market for six months. Use a transparent, science-based method to determine when a new drug should have a prescription period of less than 30 days due to specific safety concerns.
 9. Promote the use of preventive care drugs and vaccines by providing insurance coverage of drugs and vaccines used to prevent disease and by broadening the definition of "prevention."

B. Medical Devices.

1. Eliminate the Foreign Average Price (FAP) rule, which has achieved its goal of narrowing the differential between Japanese and foreign prices significantly. Until the rule is replaced, use industry-provided list prices and data only from the four current comparator countries, refrain from increasing functional categories subject to FAP cuts beyond those affected in 2006-2008, phase-in any cuts over two years, and maintain the maximum price cut of 25 percent and the FAP ratio of 1.5x.
2. Maintain the 4 percent “R-zone” level in recognition of the special situation for medical devices, which are grouped in functional categories.
3. Adjust the ranges of premiums to match those applied to analogous drug categories. Provide reimbursement incentives to promote introduction of new devices that face significantly higher costs due to regulatory requirements that greatly exceed those of other major developed countries.
4. Provide C1 and C2 reimbursement listings every month instead of quarterly. Provide a formal physician fee instead of a tentative physician fee for C2 devices at reimbursement listing time. For C2 devices ineligible for reimbursement, provide the formal physician fee quarterly.
5. Clarify the process by which companies can request higher reimbursement prices for products that are not reimbursed adequately.
6. Continue to create new functional categories for new devices that have certain improved functions over existing products.
7. Allow the diagnostic imaging industry, including U.S. industry, to present views directly to *Chuikyo’s* Subcommittee for the Evaluation of Medical Technology. Continue to provide incentives for adoption of advanced and less invasive diagnostic imaging techniques that expedite the identification and treatment of diseases and other health conditions.
8. Continue to hold study meetings about reimbursement issues for in-vitro diagnostics (IVDs) with industry, including U.S. industry. Continue to increase the technical fee for “quick testing of outpatients.”

C. Blood Products. Implement a reimbursement pricing system that accounts for the unique nature of plasma protein therapies, including high manufacturing costs.

III. Medical Device and Pharmaceutical Regulatory Reform and Related Issues. The United States urges Japan to implement regulatory policies that end the drug and device lags and improve patients’ access to innovative products by taking the following actions:

A. Pharmaceuticals.

1. Consult with industry, including U.S. industry, to facilitate Japan's participation in simultaneous global development of pharmaceuticals.
2. Encourage the Pharmaceuticals and Medical Devices Agency (PMDA) to continue its efforts to reduce waiting times for clinical trial consultations.
3. Work with industry, including U.S. industry, to reduce review times for new drugs by enhancing the review system's ability to conduct priority and standard reviews at the same time, improving the question-and-answer process, increasing the consistency of work within and between review teams, and upgrading the training of reviewers.
4. Encourage PMDA to consider less burdensome review requirements for drugs that already have been approved in countries that have safety standards comparable to Japan's.
5. Reduce the processing time for new drug applications before final approval by MHLW to two months or less by 2012.
6. Reduce review times for post-approval changes to the international norm of three months.
7. Improve promotion and regulatory reviews of vaccines in tandem with improvements in regulation for new medicines. Consult with U.S. industry on preventive-care medicine and vaccine issues.

B. Medical Devices.

1. Attain the annual product-review performance goals and work to ensure each reviewer achieves them. Publish performance data. Assess the performance in relation to the goals at meetings with industry, including U.S. industry, twice a year and at meetings of the U.S.-Japan Medical Devices and Pharmaceuticals Working Group every year.
2. Increase the medical device review staff each year in 2009-2013 in accordance with the Action Program for Speedy Review of Medical Devices. Attain PMDA's recruitment goal of increasing reviewers to 49 in fiscal year 2009. Increase efficiency of reviews and approvals through improved procedures and effective training.
3. Expand the scope of devices eligible for third-party review to Class 2 devices.
4. Issue guidance to speed approvals and reduce requirements for partial

changes by clarifying the minor changes that do not require regulatory approval, those that may be submitted by notification only, and those that may be noted in a yearly report. Implement a real-time review process for changes that are consistent with Food and Drug Administration practice.

5. Expand the acceptance of accelerated stability test data as the basis for product approval in all cases where accelerated testing methods are validated by scientific evidence, based on the notification issued by MHLW on September 5, 2008.
6. Allow bundling of device applications where scientific and regulatory issues can be most efficiently addressed in one review. Permit bundling where devices or indications for use are similar, supporting data are similar, and reviews can be done by the same group of regulators.
7. Simplify requirements for raw material data in submissions and eliminate from Notification 19 the requirement to specify the chemical composition of raw materials. Ensure Japan's requirements for biocompatibility testing are fully consistent with ISO 10993.
8. Use a system for simple registration of foreign factories in harmonization with international practices in lieu of the current accreditation system.
9. Replace the product-specific Quality Management System (QMS) conformity assessment system with a factory-specific periodic QMS.
10. Streamline IVD approvals by eliminating the pre-approval evaluation of IVDs by the National Institute of Infectious Diseases as part of reviews. Set a rule allowing IVDs to be used between clinical trial and reimbursement.

IV. Blood Products. With the aim of increasing the access of patients to life-saving blood plasma therapies, United States urges Japan to:

- A. Allow labeling to reflect country of origin and eliminate the system of "voluntary" or "non-voluntary" labels.
- B. Ensure that neither the Supply and Demand Plan nor other measures restrict the import of plasma protein products.
- C. Increase efficiency of reviews through measures such as expediting approvals of minor changes in the manufacture or structure of blood products.
- D. Improve communication to ensure U.S. industry and other stakeholders have opportunities to provide meaningful input to regulatory authorities.

V. Nutritional Supplements. The United States urges Japan to:

A. Regulatory Categories and Claims.

1. Develop a new regulatory category allowing for ingredient-specific health claims that is consistent with the regulatory frameworks of other industrialized nations, including provisions for disqualifications of products not eligible to bear the claim.
2. Based on scientific risk assessment, work with relevant stakeholders, transparently review and/or revise the list of nutrients and potency levels for Foods with Nutrient Function Claims (FNFC) based on scientific risk assessment.
3. Work with industry, including U.S. industry, and other stakeholders to find ways to improve the transparency and inclusiveness of the approval process for Foods for Specified Health Uses (FOSHU) so that the category is more practical for companies to use.
4. Continue to work with industry in a timely manner to establish and implement a system to provide information from the National Institute of Health and Nutrition's database to consumers as recommended by the Office of Trade and Investment Ombudsman.

B. Health Food Safety Regulations.

1. Improve transparency by providing meaningful opportunities to industry, including U.S. industry, and other stakeholders for input during the development of regulations related to the safety of health foods, including opportunities to participate as members of government-sponsored study groups or panels.
2. Clarify the process and criteria by which a new ingredient in a nutritional supplement is classified as a drug ingredient, a food ingredient, or a food additive and consider ways to improve the process by comparing the best practices of other industrialized nations.

C. Food Additives.

1. Maximize the use of existing scientific reviews and assessments including those by national and international bodies to reach timely completion of new and revised food additive applications in a science-based and transparent manner.
2. Improve the consistency of the process for clearing shipments that have been stopped at quarantine stations due to naturally occurring traces of substances classified as food additives, such as benzoic acid and sorbic acid, and develop ways to address the issue systematically.

D. Import Issues.

1. Continue to consider industry input on ways to make the food import process more efficient.
2. Address other long-standing concerns related to the import of nutritional supplement products.

VI. Cosmetics and Quasi-Drugs. The United States urges Japan to:

A. Quasi-Drugs. Increase the transparency and efficiency of the quasi-drug approval process by:

1. Introducing new product standards that take industry input into consideration.
2. Developing a process to regularly update and publish lists of active ingredients and of inactive ingredients approved in previous quasi-drug applications.
3. Streamlining pre-approval requirements for inactive ingredients to be consistent with regulatory frameworks in other industrialized nations.

B. Advertising and Labeling. Enable Japanese consumers to make more informed decisions by:

1. Allowing additional claims for cosmetics that are within the scope of currently approved claims and that are supported by scientific data, such as a claim regarding reducing the appearance of fine lines due to dryness.
2. Allowing additional claims for quasi-drugs and for cosmetics supported by scientific data, such as those allowed for other products regulated by the Pharmaceutical Affairs Law.

C. Other Transparency and Regulatory Issues. Improve transparency and efficiency of the quasi-drug and cosmetics regulatory systems by:

1. Providing opportunities for industry, including U.S. industry, to exchange views with the participants of the Local Advertisement Controllers' Meetings (*Rokushakyo*) at the end of or on the margins of those meetings.
2. Working with industry to develop ways to streamline the import process and implementing them in a timely manner.
3. Improving the Ministry of Health, Labor and Welfare's website to include additional information in an easily accessible location for consumers and for industry on the regulatory systems for quasi-drugs and cosmetics.

FINANCIAL SERVICES

- I. Specific Measures:** The United States recognizes the Government of Japan's Better Markets Initiative, Better Regulation Initiative, and commensurate efforts to engage with market participants in a wide range of financial services. The United States supports Japan's aims to take steps to become a global financial center, and further calls on Japan to maintain its recent progress on regulatory reform in the financial services sector by adopting the following measures:
- A. Disclosure of Large Shareholdings. The United States recommends that Japan review the revisions to institutional investor disclosure rules for shareholdings in excess of 5 percent as they apply to portfolio institutional investors who are trading without seeking control over a business, particularly with regard to reducing the frequency of required reporting, easing administrative burdens (including through technological improvements) and reducing the scope for leakage of proprietary data and related speculative activity.
 - B. Credit Bureaus. The United States requests an ongoing effort to modernize the credit information system by creating and implementing a comprehensive consumer and small business credit information system covering all sectors of financial services. An effective regulatory framework that enables the collection of, and provides access to, comprehensive full-file credit information is necessary to achieve this objective. Such a system would foster use of credit information for score development and use of score-based risk management to offer credit to consumers and businesses, including decisions to extend credit beyond pre-set income-based limits, thus promoting sound credit underwriting, deterring excessive lending, and improving consumer welfare and competitive credit markets.
 - C. Defined Contribution Pensions. In recognition of the importance of, and the value of improving, the national defined contribution pension system in terms of securing income for the elderly, labor mobility, and investment education, the United States encourages Japan to continue its efforts to improve the defined contribution pension system. Specifically, the United States recommends that Japan: (1) increase the tax-deductible contribution limits to 60,000 yen per month, based on the projected gap in defined benefit pensions targets and the required replacement rate for pension incomes; (2) allow employee contributions; (3) allow early access to funds before the age of 60 in specific circumstances; (4) allow investment advice service to be made available to participants; and (5) introduce a defined contribution pension scheme for public sector employees.
 - D. Opt-Out for Customer Information Sharing. The United States suggests that, under the current firewalls deregulation, reasonable opt-out restrictions for institutional clients should still allow the broad sharing of client information across affiliate lines for risk management, sound business practices and control purposes, authoritative senior management, and other appropriate purposes. Practical and efficient approaches to inform institutional clients of their right to opt out should be introduced.

E. Online Financial Services. The United States welcomes the Financial Services Agency's (FSA) better markets initiative, and urges consideration of the following online financial services elements:

1. Modifications to the exchange transaction definition to permit non-bank payments providers to engage in exchange transactions such as remittances and online payments.
2. Clarification of the regulatory framework to facilitate open-loop electronic stored value or e-money similar to the European Union or United States.
3. As exchange transactions fall under the bank regulation and could be interpreted to prohibit provision of simple peer-to-peer payments without a bank license, consider global best practices for pre-paid and stored value oversight.

II. Transparency

A. The United States recognizes the FSA's ongoing efforts to engage in dialogue with the private sector, and appreciates the FSA's publication of periodic progress reports on Better Regulation. While regularized discussion provides one basis for the exchange of viewpoints, official written interpretations reduce uncertainty, enhance compliance and allow for productive innovation by financial services providers. The United States encourages the FSA to continue to enhance the effectiveness of written interpretation, including the no-action letter and related systems, including by:

1. Encouraging FSA staff to promote more active use of the no-action letter system, such as by indicating receptivity to no-action letter requests to firms that seek oral advice on how to interpret Japanese laws, especially on matters where the FSA's internal interpretation is settled but no public interpretation is available.
2. Making more active use of the interpretive letter system, which allows interested parties to seek interpretations on issues beyond those covered by the no-action letter system and may include requests for clarification of laws and regulations governing existing products and services. Specifically, the United States recommends that Japan use the interpretive letter system to provide written interpretations on issues about which FSA officials have received informal oral inquiries and about which there may be some misinterpretation; and publish both positive and negative responses to no-action letter requests.

B. Establish other means to provide written interpretations of Japan's financial laws even when an interpretation has not been formally requested.

- C. A transparent and predictable rule interpretation and inspection process is critical to sound development of financial markets and to the appropriate balance among consistency, innovation and consumer and investor protection. The United States encourages the FSA to consult with foreign financial institutions and financial sector industry associations regarding concerns or potential improvements related to the inspection process, recognizing the sensitivities that individual companies may have regarding disclosure of company-specific inspection experiences.

COMPETITION POLICY

I. Improving Antimonopoly Compliance and Deterrence

- A. Strengthen Measures to Address Hard Core Cartel Violations. In order to boost deterrence against hard core cartels, amend the Antimonopoly Act (AMA) to:
1. Augment the base surcharge level for cartel and bid rigging behavior to a minimum of 15 percent of sales attributable to the unlawful practices, at least for companies that play a leading role in the conspiracy;
 2. Extend the current three-year statute of limitations for the application of cease and desist orders and surcharge payment orders to five years from the date of the last unlawful act;
 3. Increase the maximum prison sentence for violations of Article 89 of the AMA to five years, and thus the statute of limitations to five years; and
 4. Ensure that all companies that are majority-owned by the leniency applicant and, where appropriate, the parent of the leniency applicant, can jointly file a leniency application and be assigned the same order of priority.
- B. Minimize Unintended Deterrence of Procompetitive Unilateral Conduct. In order to minimize over-deterrence of procompetitive unilateral conduct:
1. Maintain the current system of remedying unfair trade practices and the exclusionary type of private monopolization through the imposition of cease-and-desist orders, and private damage remedies, rather than through the imposition of surcharges.
 2. Ensure, if Japan nonetheless decides to extend surcharges to certain unfair trade or exclusionary monopolization practices, that
 - a. Any such practices are clearly anticompetitive and are described by the AMA or JFTC enforcement guidelines with sufficient detail so that firms will know in advance that if they engage in specific conduct they will be subject to surcharges; and
 - b. The amount of any surcharges applicable to such conduct will be determined by the JFTC in a flexible manner that takes into account, among other factors: (a) the difficulty enterprises may have in distinguishing lawful unilateral conduct from unlawful anticompetitive behavior, (b) the seriousness and extent of the violation, and (c) the degree of harm to consumer welfare.
- C. Eliminating AMA Exemptions. To further promote competition in the Japanese economy for the benefit of consumers:

1. Complete by the end of JFY 2008 a review of the AMA exemption system for air carriers in the international aviation sector being conducted by the Study Group on the Optimal System of AMA Exemptions established by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT), with a view toward introducing legislation in the next regular session of the Diet to eliminate antimonopoly exemptions in the international aviation sector; and
2. Complete by the end of JFY 2008 an MLIT study of the continued necessity of the existing or a more limited antimonopoly exemption for international shipping.

D. Improve Pre-Merger Notification Procedures

1. Eliminate the post-stock acquisition notification requirements under the AMA and adopt a system in which mergers and stock acquisitions are, in principle, treated the same for purposes of pre-transaction notification obligations; and
2. Reconsider the proposed revisions to the pre-merger notification thresholds from the perspective of ensuring that they are consistent with the thresholds adopted by other developed countries.

E. Strengthen JFTC Economic Analysis Capabilities. Give priority to hiring and utilizing in JFTC investigations economists with post-graduate degrees in industrial organization, and consider the appropriateness of establishing an economic analysis division within JFTC to provide assistance to all JFTC Divisions responsible for enforcing the AMA.

II. Improving Fairness and Transparency of JFTC Administrative and Investigatory Procedures

A. Enhancing Hearing Procedure Credibility and Transparency. To assure the public and business community that JFTC hearing procedures are fair and impartial:

1. Complete by the end of JFY 2008 a review of the ex-post hearing examination system in its entirety, with a view to submitting legislation in the next regular session of the Diet, or taking other necessary measures within 2009, that will ensure that respondents in JFTC investigatory and enforcement procedures are afforded procedural fairness in the JFTC decision-making and appeals process; and
2. Revise the JFTC Rules on Hearings by the end of JFY 2008 to:
 - a. Require that the panel of hearing examiners for each public hearing includes at least one hearing examiner who is a legal professional and not a career JFTC official, and implement other appropriate

measures that will provide the public with confidence that hearing examination decisions are fair; and

- b. Prevent persons with a conflict of interest in a particular matter from acting as a hearing examiner in that matter, including by disqualifying as a hearing examiner persons with ties to the respondent or to any other person or entity affected by the proceedings, with a financial interest in the outcome of a particular case, or with any other conflict of interest.

B. Increasing Fairness of JFTC Investigatory Processes. To provide confidence to the business community that JFTC investigation procedures will be conducted in accordance with generally-accepted notions of fundamental procedural fairness:

1. Conduct a review of JFTC investigation procedures from the perspective of procedural fairness, as recommended by the Expert Committee on FDI Promotion, and issue a report in 2009 on what measures are necessary, in light of good international practice, to improve procedural fairness in JFTC investigations. Ensure that the review examines, among other issues, policies regarding:
 - a. Procedures ensuring that administrative and criminal searches and seizures are limited to evidence reasonably related to the particular investigation;
 - b. The ability of firms subject to search and seizure to review and/or obtain copies after the search and seizure of all evidence seized from their offices;
 - c. The extent to which attorneys should be allowed to be present during various investigation procedures; and
 - d. The provision of sufficient time for foreign respondents of proposed JFTC orders to review the evidence JFTC intends to use against them, taking into account the need to translate the evidence provided to the foreign respondent by JFTC.
2. Establish in 2009 a mechanism within JFTC to resolve complaints that rules providing for procedural fairness have not been abided by fully in a particular matter;
3. Revise JFTC Rules on Administrative Investigation procedures by March 2009 to ensure fundamental fairness in the issuance of warnings and the publication of the names of warning recipients;
4. Introduce rules and procedures for identifying documents containing communications between an attorney and his or her client relating to the

provision of legal advice that should be treated by JFTC as confidential under applicable law and that therefore will be protected from disclosure by JFTC; and

5. Strengthen procedures for safeguarding business confidential information possessed by JFTC, including by amending the AMA to allow JFTC to restrict access by third parties to such information in the case record and by ensuring that evidence provided to plaintiffs in private damage or injunction litigation does not contain such information.

III. Addressing Bid Rigging

- A. Prevent Conflicts of Interests in Procurement. Strengthen laws and other rules aimed at eliminating conflicts of interests of government officials at the central and local level that may contribute to the facilitation of bid rigging on government tenders.
- B. Improve Efforts to Eliminate Government-Assisted Bid Rigging. Implement measures by the end of JFY 2008 that will increase the effectiveness of Japan's efforts to eliminate government-assisted bid rigging (*kansei dango*), including additional measures to uncover instances of *kansei dango*.
- C. Expand Administrative Leniency Programs. Promote the adoption by all central and local government entities of an administrative leniency program that significantly or proportionately reduces the period of suspension from bidding for companies admitted into JFTC's Leniency Program.
- D. Improve Procurement Practices
 1. Expand the use by central government agencies, public corporations and municipalities of the Overall Greatest Value Method for awarding contracts; and
 2. Provide incentives that will encourage local governments to take measures to promote proper tendering and contracting for public works, including by expanding the general open bidding system, installing electronic bidding systems and establishing windows to receive complaints regarding bidding practices, including incidents of bid rigging.

COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

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

- A. Implement the Recommendations of the Expert Committee on FDI Promotion. In accordance with the recommendations of the Expert Committee on FDI Promotion, which were submitted to the Council on Economic and Fiscal Policy on May 20, 2008, announce strong measures to encourage more cross-border M&A activities in Japan, including by completing and publishing by June 2009:
1. An analysis of why the triangular merger technique has not been used more frequently by foreign investors in Japan;
 2. A systematic review of current tax rules and other aspects of the legal system applicable to M&A that may be impeding greater cross-border M&A activities, with a view towards ensuring:
 - a. Predictability and ease of use of such rules and other legal provisions, and
 - b. The availability of reasonable qualifying rules for tax-deferred treatment of cross-border M&A transactions, consistent with the need to prevent tax abuse, including with regard to (i) triangular mergers, including the recognition of gain by the acquired company in a cash transaction; (ii) reverse triangular mergers; and (iii) stock for asset exchanges that use the stock of the foreign parent corporation to acquire substantially all of the assets, and to assume substantially all of the liabilities, of a target company; and
 3. Recommendations on how those rules and/or other legal system conditions should be modified to encourage and facilitate greater cross-border M&A activities in Japan.
- B. Adopt Reasonable Qualifying Rules for Tax-Deferred M&A Transactions. Based on the conclusions and recommendations of the above-recommended review, include in the government's JFY 2010 proposed tax amendments any changes determined to be necessary and appropriate to promote greater cross-border M&A activities in Japan.
- C. Protect Shareholder Interests in Anti-Takeover Measures
1. Disseminate to the business sector the conclusions and recommendations of the Corporate Value Study Group (CVSG) with respect to appropriate corporate practices regarding the adoption of anti-takeover measures and provide training to Japanese corporations in implementing such conclusions and recommendations.

2. In accordance with the CVSG's conclusions that management has the obligation to make responsible judgments about the attractiveness of takeover bids from the standpoint of the interests of shareholders, require, or provide effective incentives to, boards of directors, such as the limitation of liability for breaches of fiduciary duties, to establish a committee composed of independent directors, rather than an outside committee composed of non-directors, to review and provide its views and recommendations on any takeover bid received by the company, as well as to include in the "position statement report" required by the amended Tender Offer System such views and recommendations and, if applicable, the reasons why those views and recommendations were not adopted by the full board.
 3. Take adequate measures to ensure that shareholder interests are adequately protected when firms engage in cross-shareholding arrangements, including through necessary revisions to disclosure requirements and accounting rules.
 4. Encourage the stock exchanges to put in place stronger measures by early 2009 to ensure that shareholder interests are not harmed by the adoption or execution of anti-takeover measures in a problematic manner, including (a) stronger disclosure rules on the adoption and actual operation of anti-takeover measures, and (b) incorporation of the recommendations of the CVSG concerning anti-takeover measures into stock exchange rules and stock exchange reviews of proposed anti-takeover measures by listed companies.
- D. Adopt Simple Redomestication Procedures. Evaluate and reach conclusions by March 2009 on feasible solutions that would enable foreign companies to use a simple procedure to merge or convert into a Japanese corporation.

II. Strengthening Good Corporate Governance

- A. Ensure the Independence of Outside Directors. Submit amendments to the Company Law by the end of 2009 that replace for public companies the requirement to appoint outside directors or outside auditors (*kansayaku*) with a requirement to appoint independent directors or independent *kansayaku*. Include in those amendments a definition of "independent director" (and "independent *kansayaku*") that, in addition to the exclusions contained in the current "outside director" definition, exclude any person who:
1. Has a "material relationship" with the company, including a person who (a) has had significant transactions with the company or is an employee of other companies that have had a significant business relationship with the company, (b) has an immediate family member who has had significant transactions with the company or is an executive officer in a company that has a significant business relationship with the company, or (c) is an employee, director or auditor of the parent company; or

2. The board of directors has not affirmatively determined to have no material relationship with the company.
- B. Provide Authority to Delegate Certain Decision-making Authority to Committees Composed of Independent Directors. Amend the Company Law to give explicit authority to the board of directors to delegate certain decision-making functions to a committee composed solely of independent directors, with the clear stipulation that board members are not released from their fiduciary duty to set up such committees appropriately and monitor their activities and results.
- C. Take Broad-Reaching Measures to Strengthen Corporate Governance. Implement the Financial Services Agency's (FSA's) "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets" by taking broad-reaching measures by March 2009 to strengthen corporate governance, including:
1. Completing a broad examination of the current legal system from the standpoint of strengthening corporate governance of listed companies, including through the solicitation and consideration of views from the foreign business community, institutional investors and other interested parties, and publishing a report that identifies legislative and/or other measures necessary to accomplish that goal;
 2. Completing a review of the implementation of the internal control reporting system and implementing measures to revise or clarify the standards for internal corporate controls; and
 3. Encouraging all of the stock exchanges to improve corporate governance of their listed companies by drawing up a road map by the end of 2008 of measures to strengthen and enhance the corporate governance provisions of the relevant stock exchange rules and guidelines, and implementing those measures by June 2009.
- D. Ensure Sufficient Protection of Minority Shareholders
1. Revise the Company Law or other appropriate laws to establish a clear fiduciary duty of loyalty on directors and controlling shareholders that would address duties regarding (a) self-dealing, including transactions between the controlling party and the company, (b) squeeze outs of minority shareholders, and (c) the appropriation of corporate opportunities.
 2. Encourage the stock exchanges to develop and implement by March 2009 comprehensive measures, including revision of their listing and other self-regulation rules, to increase the effectiveness of such rules in line with best global practices in ensuring that minority shareholders are not unreasonably disadvantaged by the actions of the board of directors or other shareholders. Specifically, encourage the stock exchanges to strengthen their rules relating to the:

- a. Dilution of the value and/or voting rights of existing shareholders through improper issuance of new shares, third party allocations that can result in a change of control, reverse stock splits and other practices; and
- b. Appointment of a sufficient number of independent directors who can represent the interests of minority shareholders, including with regard to listed companies that have one controlling shareholder.

E. Encourage Active and Appropriate Proxy Voting

1. In order to facilitate the smooth exercise of proxy voting by institutional and other investors, implement, through government laws or regulations or through Japanese stock exchanges rules, measures to require, or provide effective incentives to, all publicly listed companies to:
 - a. Participate in an electronic shareholder voting system;
 - b. Ensure that the notice of shareholder meetings and reference materials necessary for exercising voting rights, including proxy materials, is provided to shareholders at least three or four weeks before the relevant meeting; and
 - c. Disclose to shareholders the full results of proxy voting – including the number of votes for and against, and the number of abstentions – for each resolution voted upon at the annual or extraordinary shareholder meetings, including votes for reappointment of company directors.
2. Takes measures through the Ministry of Health, Labor and Welfare and the FSA to ensure that pension fund managers and investment managers are aware of and fulfill their fiduciary duties to exercise proxy voting rights for the benefit and solely in the interest of the beneficiaries of their respective investment accounts.
3. Require, either through FSA regulation or the rules of the relevant supervisory associations, that investment managers and other managers that manage investments for a large number of beneficiaries, disclose, at least to their shareholders and ultimate beneficiaries, their actual proxy voting record – including whether they cast a vote, and if so, whether they voted for or against, or abstained – on each resolution proposed at shareholder meetings of each publicly-listed company in which they have invested.

III. Achieving Legal System Reform

A. Promote the Provision of International Legal Services in Japan

1. Introduce legislation in the next ordinary session of the Diet that will permit registered foreign lawyers in Japan (*gaiben*) to form professional corporations on the same basis and with the same benefits, including the ability to establish branch offices, as professional corporations for Japanese lawyers (*bengoshi*), while ensuring the freedom of *gaiben* that form professional corporations to enter into or maintain partnership arrangements with *bengoshi*, whether or not each *bengoshi* has formed a professional corporation (*bengoshi hojin*) that are equivalent to partnership relationships now possible among unincorporated *gaiben* and *bengoshi*.
 2. Allow all law firms, including foreign law firms and their *bengoshi* and *gaiben* partners in Japan, to establish multiple branch offices in Japan without regard to whether they have formed a professional corporation.
 3. Complete by March 2009 a study by the Ministry of Justice (MOJ) of the legal implications of *bengoshi* becoming members of international law partnerships, including by research on the actual practice of international legal partnerships, and take steps to ensure that there are no legal or bar association rule impediments to *bengoshi*, whether in solo practice, in partnership with other *bengoshi* or in partnership with *gaiben*, becoming members of an international partnership of lawyers outside of Japan.
 4. Complete by March 2009 MOJ's research into whether measures can appropriately be taken to provide greater legal certainty regarding the ability of *gaiben* to act as neutrals, or to represent parties, in all international alternative dispute resolution proceedings taking place in Japan, including all arbitrations that are governed by non-Japanese law, and take steps to implement within 2009 any such measures.
 5. Ensure that *Nichibenren* and the local bar associations approve registration requests for new *gaiben* applicants within, in principle, three months of the original application date to MOJ and no later than two months after the approval date by MOJ.
 6. Remove the geographical limitation that still applies in relation to satisfying the three-year experience requirement for registration as a *gaiben*, so that all experience by a foreign attorney working in Japan for a *bengoshi* or *gaiben* is fully counted toward satisfying the three-year experience requirement.
- B. Facilitate Criminal Prosecution of Trade Secret Theft. In order to encourage victims of trade secret theft to cooperate with prosecutors in bringing criminal charges against the wrongdoers, introduce a new procedure that will ensure that the content of a trade secret will not become open to the public in a criminal trial for trade secret theft, such as by allowing a witness who is expected to disclose a trade secret to be examined without the attendance of the courtroom audience, and then providing a summary of that testimony that protects the trade secret in open court.

TRANSPARENCY

I. Public Input into Policy Development – Advisory Groups. Further steps by Japan remain vital to ensure the openness and transparency of advisory councils (*shingikai*) and other government-commissioned study groups (*benkyokai, kenkyukai*, etc.) that are commenting or making recommendations on policy and regulatory matters. The United States continues to strongly urge Japan to supplement general guidance for advisory councils outlined in an April 1999 Cabinet Decision with specific requirements that set predictable transparency standards in the creation and management of all advisory councils and groups, including those that:

- A. Enhance publicly accessible information about advisory councils/groups by requiring related Ministries and Agencies to:
 - 1. Make public a notice of intent to form advisory councils/groups and information about the process for their establishment;
 - 2. Ensure that Japan's centralized, publicly accessible electronic list of all advisory councils/groups and their members is inclusive of all government-appointed advisory councils/groups; and
 - 3. Make detailed minutes of advisory council/group meetings and meeting materials publicly available in principle.
- B. Require related Ministries and Agencies to provide interested parties the opportunity to provide input into the deliberations and recommendations of advisory councils/groups, including by:
 - 1. Ensuring that all interested parties have meaningful opportunities to participate in such councils/groups to the maximum appropriate extent, including throughout the deliberations by such councils/groups; and
 - 2. Providing ample advance public notice prior to council/group meetings to enable interested parties to prepare for and attend discussions.
- C. In addition to steps outlined above, the United States continues to recommend that Japan, on a centralized basis, develop before the end of 2009 a guide of best practices to improve advisory council/group transparency, and actively promote the use of these best practices by all Japanese ministries and agencies.

II. Public Comments. As Japan implements its Public Comment Procedure (PCP), the United States strongly encourages Japan to monitor the impact of the Administrative Procedure Law and take new steps to enhance the effectiveness of the system.

- A. To improve the current PCP system, the United States recommends that Japan:

1. Make proposed regulations public at the earliest possible time to allow interested parties sufficient time to analyze issues and prepare comments;
 2. Provide adequate public comment periods (30 days minimum, 60 days in principle) and, in cases where an urgent need for a shorter period exists, provide clear written explanations; and
 3. Ensure Ministries/Agencies fully consider comments and allow sufficient time to incorporate them, as appropriate, into final regulations as well as respond to submitted comments in a timely, meaningful manner.
- B. The United States recommends that the Japanese Government continue to conduct surveys of the implementation of the PCP and issue guidance on its implementation; in addition, undertake a thorough evaluation of the effectiveness of changes in the Administrative Procedure Law related to the PCP, publicly report the findings of that evaluation, and provide opportunities for public input on the system as a part of that survey process.
- C. Japanese ministries and agencies from time to time have voluntarily opened draft reports, draft legislation, and other such documents to public comment that are not formally required under the PCP system. The United States welcomes such proactive steps to heighten transparency whenever taken and encourages Japanese ministries and agencies to continue such practices to the extent possible.
- III. Transparency in Regulation and Regulatory Enforcement.** To ensure the private sector has information about regulations and information necessary to stay in compliance with regulations, including Government interpretations of such, the United States recommends that Japan require Ministries and Agencies to make public their regulations and any statements of policy or generally applicable interpretations of those regulations.
- IV. Promote Transparency in the Reorganization of Government Functions.** To support the goal of enhanced consumer protection by ensuring that predictability, effectiveness, and full clarity in Ministry and Agency roles and responsibilities are fully secured in the proposed re-organization of government functions relating to consumer protection, take steps to secure transparency throughout the process including by, for example:
- A. Opening draft legislation, draft regulations, and other aspects of the rulemaking process to meaningful public input and comment to the extent possible before final decisions are made; and
 - B. Ensure that related advisory council/group processes related to the establishment and functioning of a new organization are made fully transparent and open to meaningful public input.
- V. Foreign Translations of Japanese Laws.** The United States encourages Japan to continue with its program of translating into English its laws of greatest interest and, as it does so, continue to closely consult with the foreign business community.

OTHER GOVERNMENT PRACTICES

- I. Government Practices Relating to Agriculture.** The United States looks to Japan to ensure that it is complying fully with its international obligations in agricultural trade and thus adopt science-based, international standards in its import regimes for all agricultural and food products. In this regard, the United States recommends that Japan take all necessary additional steps to enhance the efficiency of its trading environment and the transparency of relevant rules and regulations for agricultural products, including by:
- A. Implementing a Maximum Residue Limits (MRL) regime that ensures that any mitigating measures are the least trade restrictive possible, provide national treatment to imports, and are in accordance with international practices.
 - B. Applying science-based standards to assess the safety of production substances used on organic crops and to modify the current pesticide residue policy with the goal of enhancing organic trade.
 - C. Completing the review of 46 food additives that are recognized as safe by Joint FAO/WHO Evaluation Committee on Food Additives and used throughout the world. To date, the reviews of 24 food additives have not been completed.
 - D. Completing bilateral work already underway to implement a plant quarantine system that harmonizes the classification of plant pests and diseases based on the International Plant Protection Convention standards for official control and risk analysis.
 - E. Applying international practices to Japan's enforcement program for pre-harvest and post-harvest MRL testing for specific pesticides by not considering post-harvest pesticides as food additives through the implementation of a single MRL for pre- and post-harvest use patterns.
- II. Wind Power Projects.** Consolidate regulation and oversight of wind power unit construction under a single regulatory authority.
- III. Special Zones.** The United States requests that Japan further expand the Special Zones for Structural Reform program and, wherever possible, apply Zone measures nationwide.
- IV. Consular Issues**
- A. Re-entry Permits. The United States encourages Japan to take steps to change immigration regulations so as to require re-entry permits only for trips outside Japan that are of particularly long duration, such as those lasting a year or longer.
 - B. Domestic Employee Visas. American citizens living in Japan complain that there are unreasonable restrictions on the visa issuances of business executives' personal/domestic employees. The United States requests that Japan give due

consideration to such concerns within the foreign resident community and work wherever possible to find solutions to improve the situation.

- V. Insurance Cooperatives (*Kyosai*).** The United States recommends that Japan adopt measures to improve the *kyosai* system of insurance providers. *Kyosai* hold a significant market share in Japan's insurance market and compete directly with Financial Services Agency (FSA) regulated insurance providers while avoiding many of the regulatory safeguards required of FSA-regulated insurance providers. Improving the regulatory environment for *kyosai* will benefit consumers and the Japanese insurance market by helping to ensure a sound and transparent regulatory environment.
- A. Ensure that within five years from the date of enforcement of the Small Amount Short-term Insurance Provider (SASTIP) system (*April 2011*), the FSA conduct a review of the SASTIP system as stipulated in the Amended Insurance Business Law (IBL). To contribute to an effective review of the SASTIP system, the review should provide relevant information and meaningful opportunities for insurance companies, including foreign insurance companies, and other parties concerned to participate. Such *kyosai*, to the extent that they directly compete with FSA-licensed insurance companies, should be regulated as insurance companies under the IBL and treated consistently with FSA-regulated insurance providers. Remaining unregulated *kyosai* should be monitored by the FSA to determine if they should be subject to the IBL.
- B. Evaluate the consistency of regulation and supervision among *kyosai* that are regulated by various ministries other than the FSA to determine conformity to FSA standards of supervision for private insurance service providers. Such a review should be undertaken in the near-term and in a transparent manner with meaningful opportunities for interested parties to express and exchange views.
- C. Ensure the establishment of equal conditions of competition by requiring *kyosai* regulated by various ministries to: (1) pay the same taxes as their private-sector competitors; (2) contribute to a safety net system to protect depositors and policyholders from potential failures; (3) follow the same rules and regulations as FSA-regulated insurance companies including the same reserving rules; and (4) submit to FSA supervision.
- VI. Bank Sales of Insurance.** In September 2007, the FSA found “no significant violations” of the safeguards with regard to banks' insurance sales practices and fully liberalized the bank sales channel on December 22, 2007. Accordingly, the United States recommends that Japan promptly conduct a review of market conduct rules, including the limits on sales of first and third sector products and treatment of customer data (including Insurance Business Law Enforcement Rules, Article 212), to ensure they do not limit the bank sales channel's effectiveness or impede consumer convenience. While the FSA's has committed to conduct such a review within three years, the situation calls for a more expedited review. Further revision of market conduct rules would maximize consumer benefit by promoting consumer choice, which is key to achieving the goal of increased financial competitiveness

and ensuring broader access to products by consumers and to the market by foreign and other financial services suppliers.

VII. Policyholder Protection Corporation (PPC). The United States requests that Japan adopt measures to improve the life and non-life PPC to help ensure that a more efficient, sustainable safety net system is created before the current system expires, such as by:

- A. Strengthening incentives to utilize flexible approaches and encourage market-based solutions by shifting to a post-funding system, while exercising measures to use the PPC to ensure the soundness and integrity of the financial system.
- B. Considering the establishment of a safety-net for regulated insurance cooperatives (*kyosai*) through contributions to the PPC. Regulated *kyosai*, with a significant portion of the policies in force in Japan's insurance market, are not required by Japan to pay into the PPC, unlike insurance companies regulated by the FSA.
- C. Continuing to uphold its commitment to provide private sector interested parties, including foreign insurance companies, with information on their review of the PPC, as well as meaningful and timely opportunities to express and exchange views, including an opportunity to present to the FSA's related advisory groups.

VIII. Domestication of Foreign Insurance Operations. The United States recommends that Japan take measures to ensure foreign incorporated insurance companies operating branches in Japan that wish to transfer business operations to a Japan-incorporated entity can do so in a seamless manner that protects policyholders and creditors while ensuring business continuity. Namely, revise the IBL portfolio and transfer provisions to:

- A. Create a system to permit "overnight" reorganization by eliminating or creating exceptions to the sales blackout rule.
- B. Establish statutory disclosure, notice and deemed approval procedure with all creditors.
- C. Allow the transferee entity to assume all assets and liabilities of the transferring entity in transactions approved by FSA and creditors.
- D. Permit a "deemed license" (*minashi menkyo*) assumption of regulatory licenses and approvals on condition that the transferee entity can demonstrate in the FSA review of the transaction that it will satisfy the same prudential conditions and business methods as the transferor after the transfer's completion.

IX. Independent Agents. The United States requests that Japan consider new measures to increase the competitiveness of third-party distribution channels for insurance products, such as by taking steps to mitigate the impact of taxes levied on transactions between independent agents and financial institutions that do not apply in cases of direct sales.

PRIVATIZATION

I. Privatization of Japan Post. The United States recognizes the continued efforts by Japan to implement the privatization of Japan Post and welcomes all steps to ensure consistency with market-based principles and transparency. As the process of privatization continues, the United States urges Japan to continue to take all necessary measures to ensure equivalent conditions of competition between the new Japan Post entities and the private sector, consistent with the Postal Privatization Law.

A. Level Playing Field for Postal Savings and Postal Insurance. As of October 2007, the Japan Post companies commenced with the privatization process, which requires Japan Post Bank and Japan Post Insurance to cease offering products that carry government guarantees and that they be required to meet the same tax, legal, and regulatory obligations and be subject to the same supervision and disclosure standards as private sector companies. The United States urges Japan to take the following steps to help ensure equivalent conditions of competition between the new Japan Post entities and private sector counterparts, consistent with the Japan Post Privatization Law:

1. Ensure sufficient personnel and other resources from the regular supervisory staff of the Financial Services Agency (FSA) are provided to ensure the FSA can properly regulate the postal financial entities in a manner consistent with private sector firms on a national treatment basis with other market participants.
2. Take measures to ensure that Japan Post Network's relationship with the Japan Post Bank and Japan Post Insurance are undertaken in a fair manner and on a commercial basis consistent with rules and regulations applicable to the private sector.
3. Continue to ensure the full and complete separation and financial disclosure of pre-privatized accounts and contracts from accounts and contracts concluded after October 1, 2007, and that the deposit and reinsurance contracts are on a commercial basis to prevent any cross-subsidization between the Incorporated Administrative Agency Management Organization for Postal Savings Postal Life Insurance (Public Successor Corporation) and postal financial institutions.
4. Carefully monitor actual sales practices of Japan Post Insurance and Japan Post Bank and ensure contracts initiated from October 1, 2007, are not misrepresented as having a government guarantee, as well as ensure the postal financial institutions do not leverage their relationship with the government to provide them an advantage over their competitors in the marketplace.
5. The Japan Fair Trade Commission, as appropriate, should continue to ensure that the privatization process is undertaken in a manner that promotes free

competition and effectively enforce competition policy.

B. Conditions of Competition and the Introduction of Products. The establishment of a level playing field between the postal financial institutions and private sector financial institutions is a cornerstone of the privatization process. A level playing field will promote efficient markets and contribute to the competitiveness of Japan's financial services industry.

1. The United States continues to urge Japan to ensure equivalent conditions of competition between the postal financial institutions and private financial institutions before the postal financial institutions are permitted to introduce new or altered insurance products underwritten by Japan Post Insurance, and originate new lending services and other financial products by Japan Post Bank.
2. The United States urges Japan to continue to ensure that the privatization process and implementation conform to Japan's WTO obligations, particularly the national treatment principle of the GATS.

C. Level Playing Field for Express Carrier Services. To ensure that "equivalent conditions of competition," as called for under Article 2 of the Japan Post Privatization Law, are established between government-owned Japan Post Service Company and private express carrier companies, the United States urges Japan to take the following steps:

1. Apply customs clearance procedures for items handled by Japan Post Service Company that are equivalent to those applied to private express carriers for similar actions. In particular:
 - a. Ensure that all items delivered via Express Mail Service (EMS) follow the "duty declaration" system (including using Nippon Automated Cargo Clearance, or NACCS) and not the "duty assessment" system that Japanese regulations currently apply to EMS; and
 - b. Until equivalent treatment is achieved for all EMS items, ensure that Japan's introduction of the "duty declaration" system for international postal items exceeding 200,000 yen, scheduled to come into effect by March 31, 2009, is achieved in a manner that (i) provides treatment equivalent to that provided for such items shipped by private sector operators; and (ii) will facilitate as much as possible the application of this system to all EMS items regardless of customs value.
2. Take all necessary measures to make public disclosures of the Japan Post Service Company's business, including transactions involving Japan Post Holdings and its subsidiaries, sufficient to demonstrate that cross-

subsidization among the Company's businesses (including EMS) and with other Japan Post entities does not occur, including by requiring disclosures of separate business areas to the same standards required of private firms.

3. Ensure that arm's length transactions are carried out by the Japan Post Service Company as recommended by the Postal Services Privatization Committee (PSPC) by, for example, making specific cost and business data available for independent verification of the actual existence of arm's length relationships by an appropriate organization with sufficient expertise and neutrality to make such determinations. Clarify the PSPC's role in monitoring the consistency of measures responding to PSPC recommendations.
4. Ensure equal opportunities for all private companies to access the postal network.
5. Publicly clarify the range of new businesses that Japan Post Service Company may pursue in competition with other private companies, if such were approved by the Japan Post Succession Plan and thus deemed no longer subject to further approvals/reviews.

D. Transparency. The United States urges Japan to take all necessary measures to ensure the fully transparent implementation of these reforms, including by providing ample opportunity for consideration of the views of interested parties before making final decisions, including those that affect the competitive environment in the financial services and express delivery sectors. The United States specifically urges Japan to take the following measures:

1. Provide meaningful and timely opportunities for private sector interested parties to exchange views with relevant Government of Japan officials on matters pertaining to Japan Post reforms that may affect the private sector.
2. Seek public input through the use of Public Comment Procedures and other methods with respect to draft regulations, guidelines, Cabinet and other orders, and other measures established for matters pertaining to Japan Post reforms, ensuring that input is fully considered and, where appropriate, incorporated into draft measures before they are finalized.
3. Ensure that meaningful opportunities are provided to private sector interested parties, including U.S. companies, to actively contribute to deliberations by committees or components of committees convened by the Government of Japan, including the Postal Services Privatization Committee (PSPC), on issues that may impact the private sector. Additionally, Japan should ensure that the PSPC's triennial review, to be concluded by March 2009, on the progress of Japan Post privatization is comprehensive and includes opportunities for interested stakeholders to express views, including with respect to the impact of the reforms in the banking,

insurance, and express delivery markets, and on the equivalence of conditions of competition between the new Japan Post companies and private companies.

4. Ensure that information relating to the planning and implementation of Japan Post reforms, including the discussion materials and minutes of related government-convened advisory groups, is made public in a timely way by continued use of web postings, press conferences, and other tools.

DISTRIBUTION

- I. Airport Landing and User Fees.** Although the Narita International Airport Corporation (NAA) and International Air Transport Association (IATA) discussed the reduction of landing fees and other user charges at Narita in 2005, NAA introduced a method for calculating landing fees based on aircraft noise and did not agree to significantly reduce landing fees and other charges. Moreover, some reductions were offset by other increases. To improve Japan's business and tourism climate and help boost the economy:
- A. Immediately reduce landing and user fees at Narita when NAA renews the current MOU with the industry, which will expire by March 31, 2009. A similar approach should be taken at Kansai and Chubu International Airports;
 - B. Open the formula used to calculate landing fees at Japan's international airports to a meaningful public comment process; and
 - C. Make transparent landing fee calculation at all airports for both domestic and international flights. Landing fees and other user charges should be directly related to the costs associated with the use of airport runways and facilities, as recommended by the International Civil Aviation Organization (ICAO).
- II. Improving Efficiency in Customs Processing.** The United States welcomes that Japan has formulated an Authorized Economic Operator (AEO) system in Japan. In this regard, the United States recommends the following measures be applied to customs brokers whose compliance record is good:
- A. Postmortem Declaration of Exports. Introduce a system to allow customs brokers to make export declaration after export on items of value less than 250,000 yen to facilitate a speedy, smooth export process given Narita Airport curfew hours.
 - B. Freedom to Select Customs Office for Declaration. Allow customs brokers using Nippon Automated Cargo Clearance System (NACCS) to declare express items at any convenient Customs Office beyond the territory of the Customs Office, in order to allow more speedy movement of shipments to their destination.
- III. Consumption Tax Exemption for Authorized Economic Operator (AEO) Exporters.** Although AEO exporters receive customs clearance at their premise and the cargo is regarded as "international cargo," a 5 percent tax is assessed on the movement of the cargo from the premise to the airport. Thus, the exporters have to take another process for the reimbursement of the consumption tax. For a smoother flow of cargo, the United States recommends that Japan establish a system in which AEO exporters are exempted from consumption tax payment for the cleared cargo.
- IV. *De Minimis*.** The United States strongly urges Japan to at least double the Customs Law *de minimis* limit for duty from its currently low 10,000 yen level. This change would reduce workloads for both Customs and express carriers alike and reduce customs clearance time.