

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 14, 2004

---

President George Bush and Prime Minister Junichiro Koizumi established the U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) in 2001 to promote economic growth and open markets by focusing on sectoral and cross-sectoral issues related to regulatory reform and competition policy. Now in its fourth year, the Initiative continues to play a central role in further strengthening the trade and economic ties between the United States and Japan.

The United States has been a strong supporter of Prime Minister Koizumi's bold economic reform agenda and welcomes the recent economic growth in Japan that agenda has helped to foster. The United States also welcomes Japan's continuing efforts to achieve meaningful economic reform, reaffirmed in Prime Minister Koizumi's October 12, 2004 statement to the Diet that "there can be no rebirth and development for Japan without structural reforms." Furthermore, the United States applauds Japan's decision to renew and strengthen the mandate of the Council for the Promotion of Regulatory Reform, which has been a strong and vocal advocate of wide-ranging regulatory and structural reform.

The recommendations included in this year's submission place an emphasis on reform measures pertaining to key sectors and cross-cutting areas and are meant to support the growth Japan is currently enjoying and to further open the Japanese marketplace. Furthermore, the United States has made a concerted effort to focus on issues that Prime Minister Koizumi and his Administration have identified as important areas for reform, such as telecommunications, information technologies, medical, energy, and competition policy.

In this year's recommendations, the United States has placed a special focus on privatization in Japan, which has taken on increased momentum now that plans to privatize Japan Post are going forward. Central to the United States' recommendations in this regard is the principle that privatization of Japan Post should be both ambitious and market-oriented if it is to achieve maximum economic benefits for the Japanese economy.

The United States continues to support Japan's Special Zones for Structural Reform initiative, which represents an innovative approach to promoting growth through structural reform and deregulation at the local level. The United States also welcomes recent efforts to strengthen Japan's Antimonopoly Act, urges in these recommendations the early enactment of the measures now under consideration to accomplish this, and encourages Japan to steadily improve its antimonopoly enforcement system. In addition, the United States is including for the first time proposed steps to help address the growing number of regulatory impediments in the agricultural sector.

The proposals included in the Summary of Recommendations and the Annex are being provided to the Government of Japan to serve as the basis for discussions over the coming year in the

High-level Officials Group and the Working Groups established under the Regulatory Reform Initiative. These Groups will in turn develop a fourth annual report to the President and Prime Minister specifying the progress made under this Initiative, including reform measures to be taken by each Government.

During the first three years of this Initiative, private-sector representatives periodically joined the Working Groups to provide valuable expertise, observations, and recommendations on a wide range of issues. The United States looks forward to working with Japan in the coming months to continue to actively integrate the private sector in this Initiative.

The Government of the United States is pleased to present these reform recommendations to the Japanese Government and looks forward to receiving Japan's reform proposals to the United States.

# TABLE OF CONTENTS

## SUMMARY OF RECOMMENDATIONS

TELECOMMUNICATIONS .....	1
INFORMATION TECHNOLOGIES .....	2
ENERGY .....	3
MEDICAL DEVICES AND PHARMACEUTICALS .....	4
FINANCIAL SERVICES .....	5
COMPETITION POLICY .....	6
TRANSPARENCY AND OTHER GOVERNMENT PRACTICES .....	7
PRIVATIZATION .....	8
LEGAL SYSTEMS REFORM .....	9
COMMERCIAL LAW .....	10
DISTRIBUTION .....	11

## ANNEX

TELECOMMUNICATIONS .....	Annex - 1
INFORMATION TECHNOLOGIES .....	Annex - 8
ENERGY .....	Annex - 16
MEDICAL DEVICES AND PHARMACEUTICALS .....	Annex - 25
FINANCIAL SERVICES .....	Annex - 31
COMPETITION POLICY .....	Annex - 33
TRANSPARENCY AND OTHER GOVERNMENT PRACTICES .....	Annex - 37
PRIVATIZATION .....	Annex - 44
LEGAL SYSTEMS REFORM .....	Annex - 47
COMMERCIAL LAW .....	Annex - 50
DISTRIBUTION .....	Annex - 52

---

## SUMMARY OF RECOMMENDATIONS

---

## TELECOMMUNICATIONS

The competitive environment in important parts of Japan's telecom sector has dramatically evolved over the past several years as the Japanese Government's efforts to promote policy and regulatory reform have begun to yield positive results. This is evident in the roll-out of numerous innovative technologies and competitively-priced advanced services, including Digital Subscriber Line, Fiber-to-the-Home, and Voice Over Internet Protocol. Revisions to the Telecommunications Business Law (TBL), which came into effect from April 2004, also improved the competitive conditions for this sector.

While requirements for competitive carriers have been eased significantly, the United States believes that the Ministry of Internal Affairs and Communications (MIC) should redouble its efforts to strengthen dominant carrier regulation and competitive safeguards. Without such steps, it remains difficult for competing carriers (both domestic and foreign-invested) to offer attractive alternatives to NTT's regional carriers and mobile operator. Furthermore, greater transparency and accountability is needed to ensure that decisions do not unfairly skew the regulations in favor of the incumbents. MIC could also greatly improve the competitive environment through a more transparent and pro-competitive approach to advanced wireless services, particularly relating to spectrum, in both licensed and license-exempt areas.

Building on the progress achieved in the previous year, the United States suggests that the Telecommunications Working Group continue to invite experts from government and the private sector to provide their perspectives on new and mutually important issues. In addition, the United States recommends that Japan implement the following reforms:

### **SUMMARY OF RECOMMENDATIONS**

- **Regulatory Independence:** Take steps to transfer regulatory functions to an independent agency not under ministerial authority, and end MIC's control over NTT's business decisions.
- **Mobile Termination Rates:** Investigate if rates for termination to the NTT DoCoMo network are set at reasonable, competitive levels, and ensure competitive neutrality in retail rate setting.
- **Transparency and Accountability:** Increase public participation in MIC's regulatory and policy decisions, and adopt measures to facilitate reconsideration and judicial review of regulatory decisions.
- **Spectrum Policy:** Ensure that Japan's spectrum management policies and practices (such as licensing, allocation, testing, and fees) are more transparently administered, promote greater innovation, competition, and efficient spectrum use (in both the licensed and license-exempt areas), and adhere to technology-neutral principles.
- **Strengthening of Competition Safeguards:** Bolster dominant carrier safeguards to prevent abuses by carriers with market power.
- **Equipment Certification:** Conclude a Mutual Recognition Agreement between the United States and Japan that would facilitate more efficient trade in telecommunications products.
- **Wireline Interconnection:** Address structural flaws in the 2003-2004 interconnection rate methodology, with the aim of encouraging cost-oriented and reasonable interconnection rates that promote efficient competition.

## INFORMATION TECHNOLOGIES

Japan has made important progress over the last few years in removing numerous regulatory barriers to pave the way for achieving its goal as a world IT leader by 2005, as first envisioned in a bold plan called the e-Japan Strategy. This progress has helped transform the landscape in Japan into one where broadband utilization is widespread and can be enjoyed at some of the fastest speeds available and at the lowest costs in the world. Japan has also increased the use of IT and online processes in the private and public sectors and is now one of the largest e-commerce markets in the world. While the “e-Japan Priority Policy Program 2004” (2004 Priority Policies) reaffirms Japan’s goals, it pushes forward by strategically prioritizing steps to accelerate those goals, such as ensuring secure and reliable networks, focusing on IT adoption, protecting intellectual property, encouraging development of content, and increasing use of e-government. It also acknowledges the private sector’s leadership role in promoting IT usage and the global nature of e-commerce. In its 2004 Priority Policies, the Japanese Government also recognized that legal and other barriers persist that stifle faster growth of IT usage. The United States supports Japan’s efforts to remove these barriers. It is, however, also important that Japan ensure that new strategies, laws, ordinances, and guidelines to implement the 2004 Priority Policies do not promote, mandate, or unduly favor specific technologies (technological neutrality), in order to provide maximum flexibility and encourage innovation within the private sector.

This year’s recommendations are designed to support the above goals, by focusing on: 1) removing persistent legal and other barriers that hinder e-commerce; 2) allowing maximum private-sector flexibility, innovation, self-regulation, and leadership; 3) expanding private-sector input into the development of IT-related policy, regulations, and procurement reforms; 4) creating a legal structure that enhances efficiency and security and facilitates online transactions in all areas of the economy; 5) developing coordinated policies compatible with international practice; and 6) protecting and promoting intellectual property.

### **SUMMARY OF RECOMMENDATIONS**

- **Regulatory and Other Barriers:** Remove barriers in existing laws and regulations that hinder e-commerce; ensure that new laws and policies encourage innovation in the private sector, are compatible with international practice, and promote private sector self-regulation; create a flexible legal framework for digital storage and exchange of data in various sectors; undertake coordinated, effective IT policymaking that meets the needs of the private sector.
- **IPR Protection:** Strengthen protection of intellectual property rights by extending the term of protection for sound recordings and other works; implement stronger measures to stop online piracy of digital content; jointly work with the United States in bilateral, regional, and multilateral fora to promote greater protection for IPR worldwide, especially in Asia.
- **Promotion of IT and E-Commerce:** Ensure the Privacy Law is implemented according to internationally accepted norms and in a transparent, consistent manner; promote an online dispute resolution regime that assists cross-border e-commerce; ensure that public sector network security standards and guidelines are consistent, technology neutral, and developed with ample private sector input; promote self-regulatory initiatives and technology innovation to combat spam.
- **Government IT Procurement:** Implement reforms, with concrete results, for the procurement of e-government information systems, focusing on ways to facilitate open competition, increase transparency, and promote market access for innovative online services solutions.

## ENERGY

Japan has set a positive course to expand liberalization of its retail electricity market to about 63 percent (2.4 times the 2003 level) by 2005 and its retail gas market to about 50 percent (1.25 times the 2003 level) by 2007. The U.S. Government welcomes these reforms, which are an important step in a process that should help Japan lower energy industry costs to internationally-competitive levels and provide access by consumers and commercial users to more economical electricity and natural gas.

The essential prerequisite to realizing the many benefits from liberalization is a genuinely competitive energy market that is transparent, reliable, fair and provides meaningful opportunities for new market entry. Other essential elements necessary to maintain a competitive market are effective monitoring and enforcement of regulations by authorities, as well as the development of mechanisms to continually assess conditions and implement remedies when needed.

The U.S. Government has developed recommendations intended to support the Japanese Government's reform process and help ensure that it is a genuinely competitive energy market. These recommendations are also intended to pave the way for even greater liberalization of energy markets, including down to the household level. The U.S. Government is also urging Japan to take additional new steps to improve third-party access in the energy sector (including to sources of natural gas), which is key to opening new business opportunities that in turn would spur efficiency through greater competition and innovation.

### SUMMARY OF RECOMMENDATIONS

- **Greater Third-Party Access to Natural Gas Facilities:** Establish a regulatory framework, including a tariff structure, that provides non-discriminatory, transparent, and reliable third-party access to LNG terminals and pipelines, a prerequisite to truly effective energy market competition.
- **Opportunities for New Sources of Electricity:** Boost competition and energy efficiency by establishing a regulatory environment that provides meaningful opportunities to sell electricity into the market from co-generation or other small-scale sources of excess power.
- **Monitoring the Effectiveness of Market Liberalization Reforms:** Establish assessment and monitoring mechanisms, such as independent market monitors, to ensure electricity and gas liberalization is having a meaningful, pro-competitive impact on the market; identify and remedy shortcomings in the market when they occur.
- **Opportunities for New Suppliers:** Implement strict standards of conduct on information sharing to ensure that companies affiliated with transmission and pipeline operators are not provided advantages over unaffiliated companies.
- **Fair Access to Transmission/ Distribution Facilities:** Establish procedures to supervise and enforce rules and fairness in the proposed neutral system organization (NSO); enhance steps that ensure reliable third-party access to the grid; consider introducing operational unbundling.
- **Fairness and Transparency in the Gas Sector:** Establish and strengthen a mechanism to conduct more rigorous rate approval examinations and audits; conduct neutral and fair ex-post facto monitoring.
- **Enhanced Resources for Effective Regulation:** Ensure sufficient resources are provided to undertake the tasks of developing and implementing effective regulatory functions and monitoring mechanisms; develop steps to ensure the independence of regulators and monitors.

## MEDICAL DEVICES AND PHARMACEUTICALS

In response to fiscal burdens and a rapidly aging society, Japan is continuing to reform its healthcare system. Significantly, Japan spends five times as much on healthcare for the average elderly person than for a citizen under 65, and has raised spending on elderly healthcare eight percent annually over the past decade. Improving regulatory and reimbursement pricing systems for medical devices and pharmaceuticals is a key component of Japan's healthcare reform effort. Japan, for example, is reforming its Pharmaceutical Affairs Law to speed reviews of new products and created a new regulatory body in April 2004 called the Pharmaceuticals and Medical Devices Agency (PMDA) to further this objective. Funded by an increase in user fees from medical device and drug manufacturers, PMDA has set important goals for faster product reviews. In addition, the Ministry of Health, Labor and Welfare (MHLW) has outlined plans to strengthen the competitiveness of Japan's medical device and drug industries in policy papers (called the "Visions") that recognize the value of innovation and the effects of pricing on innovative R&D investment.

The United States urges Japan, however, to continue to actively address regulatory and pricing issues related to medical devices and pharmaceuticals in order to achieve its healthcare goals. Long approval delays, for instance, raise the cost of doing business and deny patients rapid access to innovative products that improve health outcomes and cut long-term healthcare costs. Japan's reimbursement pricing rules also fail to adequately reward innovation, thereby deterring industry from conducting R&D in Japan and hindering Japan's drive to improve competitiveness. The U.S. Government encourages Japan to take steps to ensure that regulatory and reimbursement policies foster the introduction of innovative products in Japan.

### SUMMARY OF RECOMMENDATIONS

- **Pricing Reform:** Apply pricing premiums more appropriately to reward and stimulate advances in drug research and medical technology; reform pricing rules to accurately assess the value of innovative products to Japan's healthcare system and consider the needs of patients who seek fast access to innovative and safe products.
- **Regulatory Reform:** Expedite reviews and approvals by complying with important goals established by PMDA; develop in consultation with industry effective ways to evaluate if PMDA is successfully expediting product reviews; ensure that overseas audits or factory inspections do not delay approvals of new products; accept third-party inspections of medical device factories; enhance the expertise of product reviewers; identify and clarify PMDA's appeals processes for reviews and safety-related activities.
- **Blood Products:** Ensure that implementation of the Supply and Demand Plan does not discriminate against foreign products; work with industry to address issues related to blood products.
- **Nutritional Supplement Liberalization:** Deregulate the sale of nutritional supplements.



## FINANCIAL SERVICES

The U.S. Government welcomes the progress Japan has achieved over the past several years in opening its financial system to foreign and domestic competition. The Financial Services Agency (FSA), established only six years ago, has made steady progress in increasing the professionalism and transparency of financial regulation in Japan. Improved supervision, accounting standards, and regulatory transparency, together with the earlier elimination of many regulatory barriers to competition, have contributed to notable changes in Japan's financial sector. Foreign firms have increased their presence in Japan's financial markets, which have in turn become increasingly global in terms of standards and diversity of participation.

It is important that Japan continue to move forward in establishing clear and consistent regulation and supervision of financial institutions, in line with international standards and best practice. It is also important that Japan continue to eliminate unnecessary regulatory barriers to competition, consistent with the objectives of ensuring safety and soundness as well as consumer protection. A more efficient and competitive financial sector can play a crucial role in strengthening Japan's long-term economic growth potential.

### SUMMARY OF RECOMMENDATIONS

- **Financial Regulatory Transparency:** Continue the progress begun with the establishment of a No-Action Letter system by expanding the body of written interpretation of financial law through measures such as publishing more extensive and clear guidelines and producing an internet-based question-and-answer page; continue to broaden the opportunities for public hearings and comments on rulemaking and guidelines, carefully considering the comments and concerns expressed by financial firms and associations.
- **Privacy Guidelines:** Assure that the FSA Privacy Guidelines protect personal information in a manner consistent with established privacy protection systems without impeding innovation and service to Japanese customers; consider carefully the comments of interested parties, including financial firms and associations, in drafting the Guidelines.
- **Trust Bank Law:** Allow foreign bank branches to engage in trust and banking businesses concurrently, on equal footing with domestic banks under the Concurrent Operation Law.
- **Investment Trusts:** Harmonize the regulatory framework governing investment advisory and investment trust management activities; allow mergers and reduce obstacles to the early termination of investment trusts.
- **Electronic Disclosure:** Ensure meaningful disclosure while protecting consumer privacy and security by allowing lenders to satisfy disclosure requirements under the Money Lending Business Law by electronic notice, and by vigorously enforcing regulations to protect consumers from abusive practices of lenders and debt collectors.
- **Defined Contribution Pensions:** Encourage the development and adoption of defined contribution pension plans by further increases in contribution limits and by allowing employees to match the contributions of their employers.

## COMPETITION POLICY

Actively promoting competition will strengthen Japan's economic recovery by creating an economic climate that encourages new entry and innovation and fosters efficient, competitive companies. A successful competition policy depends on a strong Antimonopoly Act (AMA) and a Japan Fair Trade Commission (JFTC) that is properly equipped to uncover and challenge anti-competitive behavior in the Japanese market. It also depends on support from other Japanese government agencies to eliminate the bid rigging practices that sap public funds and undermines the restructuring of Japan's economy and to incorporate market-based competition principles in their privatization and regulatory reform efforts. New measures to strengthen the AMA have recently been the focus of intense debate in Japan. A package of measures is expected to be introduced to the Diet this fall. The United States looks forward to early enactment of those measures and hopes that Japan will continue to steadily improve Japan's antimonopoly enforcement system.

The United States therefore recommends that Japan take the following measures:

### **SUMMARY OF RECOMMENDATIONS**

- **Antimonopoly Enforcement:** Amend the AMA to increase administrative fines (surcharges) substantially, impose higher than normal surcharge rates on repeat AMA offenders; introduce a corporate leniency program that immunizes the first whistleblower from surcharges and criminal prosecution, grant JFTC compulsory investigation powers, and strengthen penalties against obstruction of investigations; prioritize for JFTC investigation conduct that clearly harms the competitive process in Japan; begin a study aimed at improving criminal sentences for AMA violations; examine further narrowing or elimination of AMA exemptions; increase JFTC resources, in particular the number of JFTC officials with advanced economics degrees; promote AMA compliance by issuing or expanding AMA guidelines and encouraging the business community to adopt effective corporate compliance programs.
- **Fairness of JFTC Enforcement Procedures:** Increase the number of judges and lawyers acting as hearing examiners; allow companies an opportunity to argue why a public warning should not be issued to them.
- **Bid Rigging Prevention:** Strengthen measures against government-led bid rigging, including stronger sanctions against government officials who attempt to instigate bid rigging; examine merits of introducing administrative leniency program that exempts from suspension of designation the first company reporting bid rigging and that protects the identity of the whistleblower; address bid rigging at the local government level through additional measures by the Ministry of Internal Affairs and Communications; improve the transparency of administrative sanctions against companies found to have engaged in bid rigging; examine the adoption of new bidding procedures designed to will make bid rigging more difficult.
- **Promoting Competition:** Ensure that JFTC's views on how to proceed in privatization in the most pro-competitive manner are solicited and that JFTC monitors entities in the process of privatization to ensure they don't engage in anti-competitive activities; seek JFTC's active participation in study groups considering sectoral reforms and have JFTC assist the work of the Council for the Promotion of Regulatory Reform.

## TRANSPARENCY AND OTHER GOVERNMENT PRACTICES

Over the years, the United States has taken up a broad range of issues under “Transparency and Other Government Practices” with the general aim of recommending ways for Japan to create a more transparent regulatory system that guarantees fairness, predictability, and accountability. Proposals to improve Japan’s Public Comment Procedures (PCP) have, for example, played prominently in past submissions as have recommendations to support the innovative efforts of the Special Zones Headquarters to revitalize local economies through establishment of deregulation zones. Demonstrating the continuing importance the United States attaches to achieving progress in these areas, reform proposals relating to the PCP and deregulation zones appear once again this year’s submission.

There are, however, several new additions to this chapter, including a recommendation for the United States and Japan to explore ways under the Regulatory Reform Initiative to achieve full implementation of the APEC Transparency Standards in the domestic legal regimes of countries in the Asia-Pacific region. The United States is also recommending that Japan undertake across-the-board liberalization of the bank sales channel for insurance products within three years and ease restrictions that hinder direct marketing of insurance to customers through banks. In addition, the United States is recommending a number of steps that would remove technical barriers impeding the import of agricultural goods into Japan.

### SUMMARY OF RECOMMENDATIONS

- **Public Comment Procedures:** Standardize a 60-day comment period or, at a minimum, impose a mandatory 30-day period; incorporate the PCP into the Administrative Procedures Law to give it the force of law.
- **APEC Transparency Standards:** Working jointly with the United States to promote full implementation of the APEC Transparency Standards in the Asia-Pacific region.
- **Special Zones for Structural Reform:** Ensure transparency remains a centerpiece of the Special Zones initiative; continue to place a focus on encouraging market entry and a priority on expeditious nationwide application of successful deregulation measures.
- **Public Input into the Development of Legislation:** Take steps to further facilitate public input into draft legislation while it is being developed by the Government and before it is submitted to the Diet.
- **Bank Sales of Insurance:** Undertake across-the-board liberalization of the bank sales channel for insurance products within three years; ease restrictions that hinder direct marketing of insurance to customers through banks.
- **Insurance Cooperatives:** Secure a level playing field between private companies and all cooperatives (*kyosai*) that offer insurance; initiate a review of regulated *kyosai* to develop level playing field reforms.
- **Government Practices Relating to Agriculture:** Remove technical barriers that impede the import of agricultural goods.

## PRIVATIZATION

The United States has taken a continuing interest in Prime Minister Koizumi's efforts to restructure and privatize Japan's public corporations, a reform initiative that can have a major impact on the Japanese economy by stimulating competition and leading to a more productive use of resources. The United States is particularly interested in Prime Minister Koizumi's ambitious efforts to privatize Japan Post. Because Japan's postal life insurance and postal saving businesses have grown to become the world's largest life insurer and savings institutions, their privatization is expected to have an enormous impact on companies operating in these sectors. Scheduled to commence in 2007, Japan Post privatization is likely to have significant implications for private express delivery companies.

Central to the United States' recommendations this year is the principle that privatization of Japan Post should be ambitious and market-oriented if it is to achieve maximum economic benefits for the Japanese economy. A truly market-oriented approach must include the establishment of undistorted competition in Japan's insurance, banking, and express delivery markets. Elimination of all advantages accorded to Japan Post over its private sector competitors is essential. These advantages have long been of concern to U.S. and Japanese companies alike. The Council on Economic and Fiscal Policy took an important step forward in its September 10, 2004 Basic Policy on the Privatization of Japan Post by recognizing the importance of equalizing the "competitive conditions" between Japan Post and private companies.

The United States looks forward to successful privatization of Japan Post and other entities such as Narita International Airport and the Japan Highway Public Corporation. This is a complex and challenging undertaking that, if carried out effectively, can bring great benefit to the Japanese economy and Japan's companies and consumers. Highlights of this year's recommendations on privatization are:

### **SUMMARY OF RECOMMENDATIONS**

- **Level Playing Field:** Eliminate all advantages accorded to Japan Post over its private sector competitors in the insurance, banking, and express delivery sectors; ensure that privatization results in undistorted competition in the market.
- **Fair Competition in Insurance and Banking:** Implement a standstill on the introduction of new or altered products and services by Japan Post's insurance and savings businesses until a truly level playing field is in place; ensure these businesses are subject to the same tax requirements, laws, regulations, reserve requirement standards, and regulatory supervision as the private sector.
- **Fair Competition in Express Delivery:** Ensure the postal regulator is independent and fully separate from Japan Post; prohibit Japan Post's postal business from receiving special government benefits that distort competition in business operations where it competes with the private sector.
- **Cross-Subsidization Prevention:** Take sufficient steps to ensure Japan Post's insurance and banking businesses do not engage in cross-subsidization with its non-financial businesses; introduce controls to prevent cross-subsidization of competitive services (i.e. express delivery) with revenues gained from Japan Post's universal postal services.
- **Full Transparency:** Ensure there are meaningful opportunities for interested private sector parties to exchange views with relevant Japanese officials on privatization and to contribute to the deliberations of related government-convened committees; ensure full utilization of Public Comment Procedures.

## LEGAL SYSTEMS REFORM

The creation of a legal environment that can respond to Japan's need for efficient international legal services and quick, inexpensive mechanisms for resolving legal disputes is important to the health of Japan's economy, particularly in ensuring a sound and effective foundation for the conduct of business transactions in the Japanese market. The United States commends Japan for its revisions of the Foreign Lawyers Law in 2003 to enable foreign lawyers and Japanese lawyers to associate freely to the benefit of Japanese consumers. The United States looks forward to the implementation of those revisions in a manner consistent with the letter and liberalizing spirit in which they were enacted. At the same time, the United States welcomes Japan's commitment to create a flexible and open legal environment that facilitates the development of Alternative Dispute Resolution (ADR) mechanisms and helps the Japanese people resolve conflicts quickly and inexpensively.

For these reasons, the United States recommends that Japan take the following measures:

### SUMMARY OF RECOMMENDATIONS

- **Freedom of Association:** Fully implement by April 1, 2005 the 2003 amendments to the Foreign Lawyers Law to allow freedom of association between Japanese and foreign lawyers; ensure that implementing rules and regulations of the Japan Federation of Bar Association are consistent with the liberalization spirit of the amendments and in particular (i) do not interfere in the ability of foreign lawyer partners to accept foreign law matters within the competence of any of their foreign lawyer associates, (ii) apply ethical rules equally to Japanese and foreign lawyers, and (iii) limit obligations on lawyer-client communications to those consistent with modern international practice and are not unreasonably burdensome.
- **Professional Corporations and Branches:** Permit foreign lawyers to form professional corporations on the same basis and with the same benefits as Japanese lawyers; allow foreign law firms and foreign lawyers in Japan to establish branch offices without being required to form a Japanese professional corporation.
- **Alternative Dispute Resolution (ADR) Mechanisms:** Adopt a basic framework for ADR that is consistent with international norms and practice, allows the parties to ADR to agree themselves on the rules, processes and standards to be applied, and permits foreign lawyers to represent parties in all ADR processes that have international elements; allow non-lawyers to act as neutrals (e.g. arbitrators, mediators, conciliators) in ADR processes without fear of violating the Lawyers Law and without the need for supervision by Japanese lawyers; ensure that any ADR licensing system is completely voluntary, does not have the effect of interfering with the legitimacy of ADR services provided by non-licensed persons or organizations, is open to foreign and Japanese persons and organizations equally, and establishes licensing and reporting procedures and standards that are not unduly burdensome.
- **Qualification Criteria for Foreign Lawyers:** Allow all of the time spent in Japan practicing home country law to count towards the three-year experience requirement for foreign lawyers.

## COMMERCIAL LAW

Effective corporate restructuring and improved corporate performance will help Japan to reposition and revitalize its economy for the demands of the 21<sup>st</sup> century global economy. The introduction of modern merger techniques in Japanese commercial law, for instance, will do much to bolster the economy by encouraging corporate restructuring and investment. In addition, the introduction of good corporate governance mechanisms will lead to improvements in corporate performance by ensuring that management works to maximize shareholder value through increased productivity and economically sound business decisions. Key to improving corporate governance is the active participation by shareholders, particularly large institutional investors such as pension funds and mutual funds. The United States welcomes the measures already taken by Japan to encourage active proxy voting by public pension funds and by investment trusts, but further actions are needed. In addition, in light of the increased shareholdings of Japanese companies by foreign investors, it is also important to facilitate the exercise of proxy voting rights by foreign shareholders.

For these reasons, the United States urges Japan to take the following measures:

### **SUMMARY OF RECOMMENDATIONS**

- **Modern Merger Techniques:** Submit legislation in the next regular Diet session that introduces modern merger techniques into Japan's commercial law, including introducing flexibility in merger currency necessary to permit the use of triangular mergers, cash mergers and share exchanges, and permitting short form (squeeze-out) mergers; take other measures necessary to facilitate mergers and acquisitions in Japan, including providing for appropriate tax treatment of modern merger techniques, while avoiding specific conditions that might unduly limit the usefulness of new merger tools.
- **Shareholder Value through Active Proxy Voting:** Promote sound proxy voting policies by public and private pension fund managers by making public the proxy voting policies of public fund managers under the auspices of the Ministry of Health, Labor and Welfare and studying whether to establish a fiduciary duty on private pension fund managers to exercise the proxies on behalf of their fund beneficiaries; encourage disclosure of the actual proxy voting records of mutual fund managers; facilitate the exercise of proxy votes by overseas shareholders by examining necessary changes to laws and rules on the exercise of proxies by subcustodians and global custodians.

## DISTRIBUTION

The United States welcomes the inclusion of distribution-related issues in Japan's new Three-Year Plan for the Promotion of Regulatory Reform, and looks forward to future efforts by Japan to advance regulatory reform of its distribution sector. The ability of producers to move goods quickly and inexpensively through customs and into consumers' hands is a key measure of economic efficiency. The United States welcomes steps taken by Japan to improve customs clearance procedures and increase competitiveness at its international ports through the reduction of customs charges nationwide. More needs to be done, however, to facilitate the flow of goods to benefit the economy and consumers. The United States therefore urges Japan to lower landing fees charged at its international airports, decrease government regulation of airline pricing and filing requirements, and improve customs processes and procedures. Similarly, expanded use of credit, debit and ATM cards benefits consumers and provides for a more smoothly operating economy. The efficiencies created by these instruments have resulted in the rapid expansion of the use of credit, debit, and ATM cards worldwide. Nevertheless, low rates of card acceptance at both traditional merchants and ATMs in Japan inconveniences Japanese residents and is a common complaint of foreign visitors to Japan. The United States welcomes Japan's recent moves to boost card acceptance at some public hospitals, and urges Japan to further promote the use and increase the security of credit and debit cards by businesses and as payment for government services.

### SUMMARY OF RECOMMENDATIONS

- **Airport Landing Fee Reform:** Immediately reduce landing and user fees at Japan's international airports and open the formula used to calculate those fees to public comment.
- **Airline Sales Distribution:** Abandon enforcement of the IATA 70-percent low band on airline tickets to benefit the consumer and increase inbound tourism.
- **30-Day Advance Fare Filing Requirement:** To give companies greater flexibility to respond to the market, eliminate the regulation stipulating fares be filed 30 days in advance and eliminate double approval pricing.
- **Free on Board Duty Calculation:** Shift from Cost of Insurance and Freight (CIF) to Free on Board (FOB) for duty calculation on low-value items, a move that would ease the work of customs officials and reduce costs in Japan.
- **De Minimis:** Raise the *de minimis* value in the Customs Law from 10,000 to 30,000 yen.
- **Reduce Customs Charges:** Continue to reduce certain customs processing charges to zero in International Physical Distribution Zones and eventually nationwide.
- **Nippon Automated Cargo Clearance System:** Ensure that NACCS takes user comments into consideration in any future changes to its fee system.
- **Credit/Debit Cards:** Further increase acceptance and security of credit and debit cards as payment for goods and services in order to benefit the economy by fostering tourism and increasing economic efficiency.

---

ANNEX

---



## TELECOMMUNICATIONS

### **I. Strengthening Regulatory Independence and Promoting Greater Transparency.**

The Ministry of Internal Affairs and Communications (MIC) has long had difficulty shielding the regulatory decision-making process from partisan influences. Previous decisions that have benefitted larger companies with histories of government ties, at the expense of new entrants, underscore the critical need for measures to bolster regulatory independence and accountability.

A. To foster regulatory independence the United States urges Japan to:

1. Develop a plan for moving regulatory functions from the purview of a ministerial agency subject to direct political control to a fully independent organization;
2. Eliminate any requirement that the Japanese Government own a specified amount of NTT shares and that foreign shareholding or a management role be restricted;
3. Eliminate ministerial interference in management operations of NTT, including business plans and personnel decisions;
4. Establish and exercise meaningful sanction authority by the regulator (imposition of fines, payments of damages, license restrictions) to punish anti-competitive behavior; and
5. Take interim steps towards achieving these goals that would include:
  - a. Implementing measures to strengthen the operation, effectiveness, and purview of Japan's Dispute Resolution Commission, including steps to maximize transparency in dispute settlement actions; and
  - b. Instituting clear firewalls between industrial promotion and regulatory oversight, to ensure that specific companies benefiting from MIC industrial promotion programs are not granted privileged regulatory treatment.

B. To foster greater regulatory accountability, the United States urges Japan to take concrete steps to facilitate reconsideration and judicial review of regulatory decisions, and ensure that the regulator and the courts have the resources to address such issues effectively within a reasonable time frame. Specifically, this should include:

1. Adopting and publishing transparent procedures to ensure that a full, public record supporting decisions and determinations is available, and

that special interests are not accorded privileged access to the regulatory process; and

2. Opening the selection process for MIC-sponsored study groups such that any interested stakeholders are given the opportunity to participate.

**II. Network Access and Promotion of Competition.** With the revision of the Telecommunications Business Law in April 2004, Japan achieved significant progress in deregulating competitive carriers. Competitors' access to bottleneck facilities, however, remains essential to promote both facilities-based and service-based competition, which are key Japanese Government goals. MIC can take further steps to ensure competition in the telecommunication sector by strengthening dominant carrier regulation, reducing interconnection rates for wireline services, and other measures that improve the competitive environment.

A. Dominant Carrier Regulation and Competition Safeguards. The United States recommends that Japan ensure that regulations and ministerial ordinances under the revised Telecommunications Business Law retain obligations specific to carriers with a dominant position in Japan's market and give the appropriate entity the authority to enforce these obligations. In particular, the United States urges Japan to:

1. Identify by March 2005 all markets and sub-markets for review of market power and appropriate remedies and establish an accelerated schedule for all such reviews, taking into account relevant experience of policy makers and regulators in other markets, such as in the EU;
2. Ensure in law and/or regulation that access to poles, ducts, conduits, and rights of way is non-discriminatory and cost-based, and provide transparent pricing methodology for such access;
3. Establish methods for evaluating pricing abuses by dominant suppliers (e.g. imputation tests) for voice as well as data services;
4. In the annual review of whether NTT East and West are complying with the parameters governing expansion into new lines of businesses, publish quantitative data relating to network access and treatment accorded competitors;
5. Institute transparent means, based on information to be made publicly available, for evaluating whether NTT East and West leased lines used by competitors are offered at reasonable, competitive rates;
6. Consider rules (e.g. separate affiliate transaction rules) to ensure that a dominant supplier does not use revenues from a regulated service to subsidize a non-regulated service in an anti-competitive manner;

7. Develop competition-related performance metrics, including reporting requirements, and financial penalties for missing such metrics. Such metrics should ensure that a dominant carrier treats competitors no less favorably than it treats itself or its affiliates in matters such as provisioning, quality of service, and repair and maintenance of all network services and facilities needed by competitors; and
8. Ensure that dominant carriers seeking to expand the scope of their services outside their traditional monopoly services be subject to appropriate safeguards to ensure that dominant position in one market is not leveraged with anti-competitive effects.

B. Wireline Interconnection. In July 2004, the Information and Communication Council released for public comment a proposal for restructuring the interconnection rate model (known as Long-Run Incremental Cost, or LRIC), which would be applicable for three years starting in FY2005. The United States welcomes the proposal as a step in the right direction towards reducing interconnection rates to acceptable levels, and looks forward to the release of the revised proposal in October 2004, which should reflect the comments received from various stakeholders. The United States urges MIC to take into serious consideration the following recommendations as it drafts the ordinances to implement the revised model:

1. *Elimination of NTS Costs*. The United States urges Japan to eliminate non-traffic sensitive (NTS) costs from the metered interconnection rates from FY2005, without a phase-out period.
2. *Review of NTT's Basic Charge*. Given the decision of NTT's two regional carriers to reduce their basic monthly charge by up to 490 yen, MIC should require NTT East and West to document, in a transparent, publicly verifiable manner:
  - a. Precisely which costs are currently recovered from monthly subscriber line charges;
  - b. Why recent basic monthly charge reductions on retail services, combined with wholesale (interconnection) rate increases are not predatory or exclusionary;
  - c. Why wholesale monthly charges (dry copper) ought not be reduced proportionately to retail rate reductions;
  - d. How costs associated with basic monthly charges are identified and allocated between different services (e.g. ISDN, DSL, leased lines etc.); and

- e. The assumptions behind basic line cost recovery, including *inter alia* cost recovery already achieved through initial subscriber line charges (*kanyu kenri* or *shisetsu secchi futankin*), depreciation rates and methodologies used, and allowable profit margins.
3. *Elimination of Subsidy Between NTT East and West.* The United States urges Japan to:
- a. 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, as necessary, permit differential interconnection rates between the regional carriers, taking into account dangers of (and methods to prevent) anti-competitive price squeezes; and
  - b. Eliminate the current use of interconnection revenue as a source of cross-subsidization between NTT East and West, and require that any such subsidies, if demonstrated to be necessary, be paid out of a competitively-neutral universal service fund.
4. *Adapting to New Market Conditions.* As the structure of Japan's wireline communications sector continues to undergo significant changes brought on by competition and innovation, the United States urges Japan to:
- a. Consider transitioning to a bill-and-keep cost-recovery mechanism for as broad as possible a range of network access functions; and
  - b. Ensure that carriers can request assistance from the Telecommunications Business Dispute Settlement Commission to resolve disputes regarding negotiated interconnection for voice calls carried between analog systems and IP-based networks, as well as between carriers providing IP-based voice telephony, taking into account the market power of dominant carriers.
- C. Mobile Termination Rates. The United States urges Japan to:
- 1. In accordance with Japan's Telecommunications Business Law and Japan's 2002 commitment to ensure competitive interconnection rates for dominant wireless networks, institute an objective and transparent means for evaluating whether mobile wireless termination rates are set at cost-oriented levels, and to provide a basis for arbitration if commercial negotiations fail;
  - 2. For wireline carriers seeking to interconnect with mobile operators, institute competitive neutrality by eliminating the default right of mobile carriers setting the retail rate; and

3. In addition to analyzing NTT DoCoMo's dominant position in the mobile sector, analyze the degree to which all mobile carriers exert market power in the sub market for call termination.

D. Promotion of Competition in the Mobile Sector. Given the high degree of concentration in Japan's mobile market, and high consumer prices, the United States urges Japan to consider expanding opportunities for additional mobile operators to enter this market, including in the 2010 and 800 MHz bands. Where incumbent operators are underutilizing spectrum, or are in the process of moving subscribers to new services in different spectrum, MIC should consider re-allocating older spectrum to other operators on a technology-neutral basis.

E. Deregulation of Digging Regulations. Institute a review of all digging regulations, based on a public comment process, with a view to identifying which rules can be relaxed or eliminated to help reduce the cost and time involved in installing new telecommunications infrastructure.

F. Unbundling. Prior to eliminating any unbundling requirements, conduct a market review based on competition policy principles, incorporating public comments, to evaluate relevant instances of market power and bottleneck control.

G. Non-Discrimination in Service Quality. For facilities where unbundling is required, the United States urges Japan to require NTT East and West to:

1. Include among their interconnection terms and conditions a service level agreement (SLA) similar to those offered to retail customers, specifying the period within which NTT East and West must respond to a disruption or deterioration of service; and
2. Permit wholesale customers the option of maintaining facilities themselves, subject to reasonable access to such facilities.

**III. Measures to Promote Advanced Wireless Technologies and Services.** In its 2004 White Paper, "Building a Ubiquitous Society That Spreads Throughout the World," MIC described how broadband and wireless technologies are converging in Japan to create "ubiquitous networks that allow anyone to connect to networks at anytime from anywhere and exchange information freely." Furthermore, in August 2004, MIC announced that its FY2005 ICT policy will focus on the "u-Japan" paradigm. Consistent with these goals, the United States recommends that Japan adopt more flexible approaches to spectrum regulation in order to promote innovation, competition, transparency, and efficient spectrum use. Specific recommendations include:

A. Flexible Use of Licensed Spectrum. To encourage more efficient and innovative use of spectrum, the United States recommends that Japan:

1. Take steps to facilitate the ability of licensed operators to lease, sub-lease, and exchange spectrum with other service providers; and
  2. Institute a clear policy of technology-neutral licensing, separating, to the maximum extent possible, operator choice of technology from the spectrum assignment and service license process.
- B. Spectrum Allocation For New Technology. The United States urges Japan to
1. Begin identifying and allocating spectrum that can be used for innovative wireless LAN technologies, fixed and mobile MAN services and other non-standardized technologies; and
  2. Consider, where feasible, making spectrum available for such technologies on an unlicensed or “license-exempt” basis.
- C. Testing Procedures For New Technologies. Review procedures for obtaining test licenses with a view to streamlining the process, making it more transparent, and establish procedural safeguards that prevent incumbent companies from hindering the testing of competing technologies.
- D. Spectrum User Fee System. As MIC reviews the proposal by the Study Group on Policies Concerning the Effective Radio Spectrum Use, and finalizes its decision, the United States urges MIC to:
1. Refrain from imposing user fees on license-exempt devices and services; and
  2. Refrain from introducing new forms of spectrum exclusivity for license-exempt devices until non-exclusivity options have been thoroughly and transparently examined.
- E. Spectrum Use by Unlicensed Low-Power Devices. The United States urges the Japanese Government to ensure a timely, objective, and transparent process for the deliberation of regulatory changes in FY2004 and thereafter that would allow use of spectrum on license-exempt basis for low-power RFID devices, taking into consideration interests of existing users in the relevant bands.
- F. Private Sector Input. The United States looks forward to enhancing the Telecommunications Working Group dialogue by inviting experts from government and the private sector as guest speakers to share their views.

**IV. Promotion of Trade in Telecommunications Equipment.** To facilitate more efficient trade in telecommunications and IT products, both the United States and Japan have taken steps to facilitate mutual recognition of testing and certification requirements. In this spirit, the United States proposes that through the Telecommunications Working Group,

the Governments of the United States and Japan conclude a Mutual Recognition Agreement (MRA) for requirements relating to telecommunications equipment specifically, and electro-magnetic compatibility (EMC) generally by the end of FY2004.

## INFORMATION TECHNOLOGIES

- I. Removing Regulatory and Non-Regulatory Barriers.** Promotion of e-commerce remains a key priority for Japan in its e-Japan Priority Policy Program 2004 (2004 Priority Policies). Japan has made great strides in increasing the use of online processes in the private and public sectors. Legal and other regulatory barriers, however, remain that prohibit Japan from fully realizing its IT potential. The 2004 Priority Policies acknowledge that structural reform, as one of the keys to restoring the overall health of the Japanese economy, is a critical element of the e-Japan Strategy II, and that the Government must promote free and fair competition to better support the private sector. In line with these policies and goals, the United States urges the Japanese Government to:
- A. Remove barriers in existing laws and regulations that hinder e-commerce, such as requirements for face to face or paper based transactions and other hindrances to e-commerce and online services; and amend laws and regulations as necessary to allow electronic notifications and transactions in sectors in which they are currently barred. The United States, for example, urges Japan to:
    - 1. Permit e-notification under the Money Lending Business Law; and
    - 2. Amend the Road Transportation Vehicle Law to allow registered owners of fleet vehicles to use online e-government systems to change fleet vehicle registrations and register title transfers independently of the registered user's application for change of the description in the certificate of vehicle inspection, and allow these changes to be made in a more reasonable time frame.
  - B. Ensure that new laws, ordinances, and guidelines enacted to implement the 2004 Priority Policies, including policies related to central and local governments' use of IT and international cooperation on IT strategies, do not promote, mandate or unduly favor specific technologies (technological neutrality), in order to provide maximum flexibility and encourage innovation within the private sector.
  - C. Ensure that new laws, ordinances, and guidelines enacted to implement the 2004 Priority Policies related to e-commerce are consistent with international practice and maintain the principle of private sector self regulation.
  - D. Create a flexible legal framework for digital storage and exchange of data in various sectors, including medical services, through passage of the proposed "e-Document Law" and its implementing regulations. The United States recommends that the Japanese Government continue to:
    - 1. Ensure that any forthcoming regulations or guidelines by various ministries related to the "e-Document Law" are developed in a coordinated manner and implemented consistently; and



2. Maintain transparency and facilitate private sector input by providing a minimum 30-day public comment period, taking into serious consideration the comments received, and reflecting this input as appropriate in the final measures.
- E. Implement measures to strengthen the ability of the IT Strategic Headquarters to produce coordinated, effective IT policymaking that meets the needs of the private sector, such as:
1. Ensure close cooperation between the IT Strategic Headquarters and the Council and the Headquarters for the Promotion of Regulatory Reform as the reforms proposed in the 2004 Priority Policies are pursued;
  2. Promote private sector input into the IT Strategic Headquarters and its Expert Committee on IT Strategy Evaluation. This includes actively seeking input in a transparent manner from private sector experts, including those from non Japanese entities, under the newly established e-Japan policy program evaluation system (the “Plan Do Check Act” cycle); and
  3. Ensure that the Inter Ministerial Task Force on IT (*renraku kaigi*) has the resources needed to facilitate the systematic, coordinated, and comprehensive implementation of IT policy by ministries and agencies.

**II. Strengthening the Protection of Intellectual Property Rights.** Japan has recognized the economic importance of intellectual property along with IT in revitalizing Japan’s economy, and is striving to become a leader in the creation, utilization, and protection of IP through the IP Promotion Plan. In line with these goals and the IP Promotion Plan, the United States urges the Japanese Government to adopt the following recommendations:

- A. Copyright Term Extension. Extend Japan’s terms of copyright protection for sound recordings and all other subject matter protected under the Copyright Law in alignment with the current global trend to life of the author plus seventy years for works generally, and to 95 years from publication for works for which the term is not based on a human life.
- B. Statutory Damages. Strengthen the enforcement system against intellectual property infringement by adopting a statutory damages system that will act as a deterrent against infringing activities, ensure that right holders are fairly compensated for the losses suffered by infringement, and enhance judicial efficiency by eliminating the costly and difficult burden of having to establish and calculate actual damages or profits.
- C. Protection of Digital Content. Build on the progress the Japanese Government has achieved in strengthening the protection of digital content and preventing online piracy by:

1. *Effective Government Oversight.* Implementing measures to ensure that all government agencies and public institutions effectively prevent and punish the unauthorized reproduction, making available, or transmission of pirated copies of works or any other infringing activities on government-supported IT resources;
  2. *ISP Liability.* Comprehensively and actively monitoring and strengthening current measures to prevent digital content piracy, including Internet Service Provider Liability Rules;
  3. *Online Piracy.* Improving effective enforcement of copyright in the online environment;
  4. *Private-Use Exception.* Clarifying the scope of the private-use exception so that activities with implications beyond the home, such as participation in peer-to-peer file sharing, are not permitted without the authorization of the right holder;
  5. *Temporary Copies.* Continue advising stakeholders of developments in the application of the Japanese Government's important recognition that "temporary storage" implicates the reproduction right, so as to provide certainty and clear guidance;
  6. *Technological Protection Measures (TPMs).* In order to stem the dramatic increase in digital piracy, enhancing the scope of protection for TPMs; and
  7. *End-User Piracy.* Expanding the scope of what is deemed infringement to ensure that all forms of end-user piracy are prohibited.
- D. Book Piracy. Take steps to effectively enforce Japan's Copyright Law to prevent illegal reproduction of books, especially on university campuses.
- E. Appropriate Scope for Education Exception Amendment to Copyright Law. Ensure the Education Exception in Article 35 of Japan's Copyright Law does not conflict with normal exploitation of copyrighted works and does not unreasonably prejudice the legitimate interests of right holders.
- F. IP Strategic Program and Intellectual Property Policies. The IP Strategy Headquarters (IPSH) issued the "IP Strategic Program 2004" on May 27, 2004. In implementing the Program and other IP policies, the United States urges the IPSH and the Japanese Government to ensure that:
1. Any Cabinet orders, ministerial ordinances, notifications, guidelines, or other measures prepared for the purpose of implementing the IP Promotion Plan, the policy goals of the "Intellectual Property Policy Outline," and any other IP-related measures are subject to the Public Comment

Procedures; that a minimum period of 30 days is provided for comments, and that comments received are seriously considered and reflected as appropriate in the final measures and actions that are implemented;

2. The implementation of the measures and policy goals is in compliance with international obligations, standards, and norms;
3. Experts from non-Japanese entities will be included in the “special committees” under Government Ordinance No. 45 to review and discuss important IP policy issues; and
4. The IPSH is provided the support, resources, and coordination mechanisms needed to successfully manage and coordinate the implementing measures between the relevant ministries and agencies.

- G. U.S.-Japan Cooperation to Improve Intellectual Property Rights Protection. Jointly work with the United States in bilateral, regional, and multilateral fora to promote greater protection for intellectual property rights worldwide, especially in Asia.

**III. Promoting and Facilitating Public and Private Sector Use of E-Commerce.** The e-Japan Strategy II and the e-Japan Priority Policy Program 2004 aim to promote IT and electronic commerce utilization throughout Japan’s economy, both to benefit individuals and to create high value added business activities. At the same time, the speed, convenience, and low cost of the Internet have made cross border e-commerce advantageous for international trade, necessitating consistent policies and regulations among trading partners. Public and private sector policies that protect personal privacy, promote ADR for e-commerce, promote network security, and control spam can contribute to the expansion of IT usage within Japan and foster domestic and international e-commerce. These policies should emphasize private sector leadership and self-regulatory mechanisms and be compatible with international practice.

- A. Privacy. Since the Diet passed the Law on the Protection of Personal Information on May 23, 2003 (Privacy Law), several ministries and agencies have formulated implementation guidelines, which must be finalized before the Law goes into effect in April 2005. The United States urges Japan to:
1. Ensure that any forthcoming privacy implementation guidelines are developed in a transparent and coordinated manner, including at least a 30-day public comment period and an appropriate amount of time to consider those comments received before finalizing the guidelines;
  2. Ensure that all final guidelines are consistent, complement existing international regulations, and are not overly burdensome, so as not to hinder e-business or B to B and B to C e-commerce;

3. Expand the dialogue on medical privacy by co-sponsoring a video conference between our privacy experts in the winter of 2005. To promote consistency, privacy experts from various ministries will be asked to participate; and
4. Ensure that each ministry developing privacy implementation guidelines enforces those guidelines consistently and fairly and establishes a system to publish information about violations and corrective actions, such as issuing authoritative government regulations and/or guidelines and examples for educational purposes.

B. Promotion of Alternative Dispute Resolution. The 2004 e-Japan Priority Policy Program includes the promotion of ADR for e-commerce.

1. The United States urges the IT Strategic Headquarters to adopt measures that promote online dispute resolution and ensure that those measures are implemented in a manner that allows ADR for e-commerce to be based on principles of self regulation that allow the parties generally to determine the rules, process, and standards to be applied in ADR proceedings.
2. In the context of the Japanese Government's efforts to develop legislation that will create a flexible and open legal environment for the development of ADR services, the United States urges Japan to adopt an ADR regime that specifically accommodates the cross-border nature of electronic commerce and that incorporates the recommendations on ADR contained in the Commercial Law Section of this submission.

C. Network Security. The February 2004 e-Japan Acceleration Package and the e-Japan Priority Policy Program 2004 call for the Japanese Government to take a variety of measures related to strengthening Japan's information security policies in the government and private sectors. The United States continues to support Japan's efforts in these areas, and encourages the Japan Government to involve all stakeholders in developing its initiatives. The September 9, 2003 U.S.-Japan Joint Statement on Promoting Global Cyber Security (2003 Joint Statement) affirms that public private collaboration is particularly important because the vast majority of critical infrastructure is owned by the private sector.

1. The Japanese Government currently is developing network security standards for central government systems. In developing these standards, the United States urges Japan to:
  - a. Coordinate standards development efforts with the private sector to increase the likelihood that the private sector will voluntarily adopt and use the same standards and guidelines as the Government;

- b. Develop and implement these standards in a transparent manner. This includes opening a draft of the standards to a minimum 30-day public comment period, allowing all interested stakeholders (both domestic and foreign) to have the opportunity to review and participate in a meaningful public comment process. The Japanese Government should review all comments received and incorporate those comments when they result in an improved document or approach; and
    - c. Ensure that standards are consistent among ministries and agencies. The Japanese Government recognized the importance of a centralized authority to develop and coordinate national cybersecurity plans and policies in a holistic intergovernmental manner in the “2003 Joint Statement.” In order to ensure consistency among ministries and agencies, the Japanese Government should support the Cabinet Secretariat’s IT Security Office with adequate resources to enable government wide coordination.
  - 2. The U.S. Government understands that the Japanese Government is considering developing network security standards for the private sector. The United States urges Japan to:
    - a. Confirm that network security standards will not be mandatory for private sector firms;
    - b. Follow the U.S.-Japan mutually recognized principle of private sector self-regulation and allow the private sector to voluntarily choose the best available standards for its needs;
    - c. Work in conjunction with the private sector to develop and disseminate best practices for network security; and
    - d. Encourage and promote the use of standards developed by international voluntary industry standards bodies.
- D. Spam. Unsolicited commercial e-mail, or spam, is generally recognized as a burden and cost for consumers and businesses alike and is also increasingly associated with various forms of online fraud and the dissemination of malicious code. The growth of e-commerce will be jeopardized if steps are not taken to address rising threats to e-commerce in the form of spam. The United States believes a combination of consumer and business education, effective law enforcement, technology standards, and best practices will be required to effectively deal with spam. As such, the United State urges Japan to:

1. Acknowledge that the private sector has a central role in combating spam through the development of innovative technologies; and that the private sector should exercise technology choice in combating spam; and
2. Pursue increased consumer awareness and effective law enforcement tools and include self-regulatory initiatives in its efforts to combat spam.

**IV. Promoting Procurement Reforms for Information Systems.** Since 2001, the Government of Japan has taken several concrete steps to reform procedures for procurement of information systems for e-government projects. These measures were recognized as necessary to accomplish such goals as discouraging anti-competitive behavior, procuring high quality e-government systems at a reasonable cost, stimulating innovation and competition among vendors, and promoting transparency and technological neutrality in central government procurement. The U.S. Government supports these goals, which were reiterated in the Chief Information Officer (CIO) Council's 2003 E-Gov Plan and the e-Japan 2004 Priority Policies. To ensure that these reforms are producing the intended results, the United States urges the Japanese Government to:

- A. Monitor and evaluate the implementation and effectiveness of the measures listed in the memorandum of agreement adopted by the ministries on March 30, 2004. In particular, the United States recommends that Japan:
  1. Use the Public Comment Procedures within FY2004 to solicit feedback from the private sector on ways to improve the information systems procurement procedures being implemented according to the memorandum, including issues that remain under consideration, such as how to clarify liability for losses and IPR ownership;
  2. Institute methods to objectively evaluate the effectiveness of measures that are designed to prevent extreme low-priced bids and other anti-competitive behavior; and
  3. Ensure that all ministries contribute information about specific cases of awarded procurements of information systems to the database established in April 2004 (*joho system ni kakawaru seifu chotatsu jirei* database). The U.S. Government encourages the Japanese Government to analyze this information and publish statistics on overall trends in information systems procurement, including:
    - a. Ratio of negotiated contracts (*zui keiyaku*) to general competitive tenders;
    - b. Adoption of new bid evaluation methods such as life-cycle cost and Overall Greatest Value Method (OGVM); and

c. Adoption of new contract methods such as multi-year contracts.

B. Adopt additional measures to strengthen the reforms of government information systems procurement, including:

1. Disclose information about procurement awards in a timely, transparent, and accessible manner;
2. Revise the qualification screening system to eliminate barriers for small- and medium-sized enterprises and foreign firms; and
3. Encourage procuring agencies to reduce contract bundling where appropriate (for example, separate tenders for hardware, software, and software development). In cases where contract bundling is necessary, take steps to mitigate the anti-competitive effects of a single tender for a prime contractor.

## ENERGY

- I. Independent Regulatory Authority.** A vigorous enforcement mechanism is key to achieving effective, pro-competitive regulatory reform of Japan's electricity and natural gas sectors. The Japanese Government recognized in the 2004 Report to Leaders the importance of securing sufficient staff, expertise, and independence to accomplish this goal. The U.S. Government therefore urges the Japanese Government to:
- A. Develop concrete steps to ensure that Ministry of Economy, Trade and Industry (METI) staffing is consistent with the sizable monitoring and enforcement responsibilities required by the Law for the Partial Revision of the Electricity Utility Industry Law and the Gas Utility Industry Law (hereafter the Law);
  - B. Provide sufficient independent budget resources to undertake adequate enforcement and monitoring;
  - C. In implementing ordinances/regulations for the Laws, clearly define the scope and division of regulatory powers and responsibilities between relevant METI regulatory divisions on the one hand, and policy-making divisions on the other;
  - D. Commit offices with energy sector regulatory and monitoring functions within METI to refrain from accepting detailees from any energy or energy service provider; and
  - E. Ensure that rules of conduct for energy sector-related METI regulatory and monitoring division personnel effectively secure independence in decision making.
- II. Monitoring and Assessment of Regulatory Reforms.** Regulatory reforms undertaken in the electricity and natural gas sectors to expand retail choice, encourage greater competition among suppliers, and create new opportunities for market entry also require careful monitoring and assessment to ensure that significant pro-competitive market impacts of these reforms are actually realized. Where shortcomings are identified over time through assessments, the process should also lead to the initiation of discussions on additional regulatory reform steps, including new structural reforms, to achieve a fully competitive market that is open to new entry. The U.S. Government therefore urges the Japanese Government to develop monitoring and assessment plans to track the actual development of market competition, dedicate the necessary resources to implement this plan, and have plans in place for electricity and natural gas sectors by summer of 2005. Steps might include establishing benchmarks in different areas to assess competition, designating market monitors to undertake ongoing independent analysis of actual market conditions and trends, and calling for regular review by related METI study groups of market information in order to consider whether further steps are necessary to achieve greater competition.



**III. Public Input and the Reform Process.** As the regulatory reform process in the electricity and natural gas sectors moves forward, the U.S. Government urges the Japanese Government to continue to provide meaningful opportunities for public input (such as through the use of Public Comment Procedures) and to ensure that these views are factored into the related final ordinances, regulations, and guidelines.

**IV. Confidentiality of Business Information.** Strict standards of conduct concerning confidentiality and the exchange of business information help prevent energy and marketing affiliates of transmitting utilities and/or pipelines from having an unfair competitive advantage over other unaffiliated marketers and energy firms. Lacking such standards, business sensitive information acquired by transmitting utilities or pipelines in the ordinary course of providing transportation services to unaffiliated marketer and energy firms could be passed along to the energy and marketing affiliates of such transmitting utilities and pipelines, undermining the confidence of investors in fair treatment and thus discouraging investment in needed energy infrastructure. The U.S. Government urges the Japanese Government to develop standards of conduct, as appropriate, that apply uniformly to natural gas pipelines and electricity transmitting utilities and that include the following principles:

- A. Expansion of the independent functioning requirements of transmitting utilities/pipelines from their energy and marketing affiliates; and
- B. Restrictions on the types of information that can be shared, as well as the types of employees, consultants and contractors that can be shared.

**V. Electricity Sector**

A. The transparent development and effective enforcement of implementing ordinances/regulations under the Law is key to a healthy, competitive, and stable electricity market. A competitive market is possible only with an adequate infrastructure, fuel supply, and generation and transmission facilities. Further, effective and transparent rules on electric companies' behavior toward competitors, rates and transmission operation are necessary in a vertically integrated electricity industry to attract needed capital investment and to ensure consumers fully benefit from liberalization. The U.S. Government therefore urges Japan to take additional steps as well as expeditiously issue concrete and detailed implementing ordinances/regulations to meet the Law's objectives.

- 1. *Adequate Market Structure to Support Wholesale Competition.* The U. S. Government recommends that METI undertake the following steps to create access to numerous generation sources through an interconnected transmission network:
  - a. Issue detailed ordinances/regulations providing transparent interconnection procedures and charges to transmission facilities for all market participants, including large and small generators,

and issuing regulations for pricing and provision of transmission support network services (i.e. ancillary services), such as load-balancing and load-following, in order to enable efficient electricity transactions and timely construction of grid-related facilities;

- b. Conduct studies to reveal possible inadequacies in the interconnection capability necessary to support a competitive national power market, and develop concrete measures to remedy such inadequacies where economical;
- c. Jointly monitor with the Japan Fair Trade Commission (JFTC) the structure of the proposed power exchange to ensure an efficient basic market design and fair and transparent rules for participation with minimal restrictions on volume and qualification of participation;
- d. Issue detailed METI ordinances/regulations as well as joint guidelines with the JFTC concerning trades on the proposed power exchange;
- e. Issue detailed ordinances/regulations requiring ex-post verification of trades by requiring members of the power exchange to report on volume and terms and conditions of trades to enable enforcement agencies to detect violations; and
- f. Require the companies of the proposed power exchange to create the position of “market monitor,” who, as an independent expert not employed by any of the companies, will audit the market on a regular basis to ensure it is competitive, ensure that the exchange’s rules and procedures rely on market mechanisms to the maximum extent possible, and write reports to METI at least annually on the state of competition in the market.

2. *Terms of Access to Transmission/Distribution Facilities.* The Electricity Industry Committee has confirmed the importance of ensuring “fairness and transparency” in the establishment of a Neutral System Organization (NSO) and in the performance of its services. The Committee also made specific related recommendations to achieve this goal. The U.S. Government urges METI to implement concrete and detailed ordinances/regulations in the following areas:

- a. Establish procedures for METI to supervise the NSO and issue orders to the NSO if necessary to correct any inadequacies, as agreed to in the 2004 Report to Leaders;

- b. Establish procedures to enforce NSO rules on the “construction of facilities, network access, system operation and information disclosure,” as identified in the 2004 Report to Leaders, including a disclosure requirement on available transmission line capacity;
  - c. Establish procedures allowing METI to enforce fairness and transparency in NSO structure and decision-making so that NSO incumbent companies are unable to dominate the organization; and
  - d. Implement periodic reviews of the NSO’s effectiveness, and introduce procedures to disband the NSO should it prove unable to reach timely, clear decisions, replacing it with a truly independent organization containing no market participants.
3. *Third Party Access to Transmission/Distribution Lines.* To effectively implement fair and transparent accounting and tariffs for third party access under the Law, the U.S. Government urges METI to adopt concrete and detailed ordinances/regulations to achieve the following aims:
- a. Separation of transmission and distribution functions from other electricity functions in order to prevent cross-subsidization, and publication of the accounting rules and the details of the separated accounts;
  - b. Elimination of transmission rate pancaking and the replacement of pancaked rates with a transmission rate calculation method that has been adopted through a public comment process; and
  - c. Allocation of costs for transmission facility expansion, taking into account the market participants’ benefits and cost burden.
4. *Implementation of Behavioral Regulation.* Behavioral regulation requires continuing oversight by METI, and by the JFTC with respect to the Antimonopoly Act, to enforce prohibitions against discrimination in the electricity industry. Specific ordinances and remedies for enforcement bolster confidence among possible new entrants in the market. The U. S. Government urges METI to adopt concrete and detailed ordinances/ regulations to:
- a. Prohibit information obtained through wheeling services from being used for purposes other than providing such services;
  - b. Prohibit unjust discriminatory treatment by the utilities’ transmission/distribution operations against other electricity firms;

- c. Prohibit unjust discriminatory treatment against rival electricity firms through denial of reasonable access to utility-owned liquefied natural gas facilities;
  - d. Conduct vigilant ex-post market oversight and settle regulatory disputes in a neutral and fair manner;
  - e. Implement a review of the effectiveness of behavioral regulations and ex-post monitoring; and
  - f. Provide for more structural methods (such as transferring control of the numerous transmission systems to an independent neutral operator) for prohibiting unjust discriminatory treatment should behavioral regulations and ex-post monitoring prove insufficient.
- B. Self-generation and co-generation by industrial companies can efficiently add supply and reliability to Japan's electricity system while making it more competitive. The Council for the Promotion of Regulatory Reform, in an August 2004 report, also highlights the importance of discussing ways to provide network connections for such sources of electricity. In order to facilitate a market where industrial producers of steam or other small generators are able to sell excess power, the U.S. Government urges Japan to implement concrete and detailed ordinances/regulations that:
  - 1. Prohibit imposition of unreasonable tariffs or interconnection charges to companies using distributed generation; and
  - 2. Require transparent specifications and procedures for interconnection, allowing industrial companies with excess output to sell power to other customers via their own or utility owned transmission lines.
- C. To expand consumer choice and investor confidence in Japan's electricity market, the U.S. Government urges Japan to establish concrete and detailed ordinances/regulations consistent with the liberalization timetables set forth in the 2004 Report to the Leaders, including possible further retail liberalization for household customers.
- D. The U.S. Government urges Japan to ensure that the privatization of the Electric Power Development Company (EPDC, also known as J-Power) is achieved in a market-oriented manner, ensuring that no special advantages are accorded to EPDC over private sector competitors, and in a manner consistent with the Antimonopoly Act.

## **VI. Natural Gas Sector**

- A. The success of the Law toward development of a healthy, competitive, and stable gas market in Japan largely depends on the transparent development and effective enforcement of implementing ordinances/regulations. Since gas fuels the majority of new electricity generation in Japan, successful gas market liberalization is also essential for healthy, stable electricity market. The U.S. Government therefore urges the Japanese Government to expeditiously issue concrete and detailed implementing ordinances/regulations to meet the objectives established in the Law.
1. *Fairness and Transparency.* To ensure fairness and transparency in Japan's gas market, the U.S. Government recommends that the Japanese Government implement concrete and detailed ordinances/regulations that establish and strengthen a mechanism for METI to conduct more rigorous rate approval examinations and audits, quickly settle disputes that occur as a result of free competition in the market, and conduct neutral and fair ex-post facto monitoring and dispute settlement, with a high degree of expertise and independence.
  2. *Neutrality and Access.* The U.S. Government urges METI to promulgate detailed and concrete ordinances/regulations that:
    - a. Obligate all pipeline owners and operators for gas supply in principle to draft, file, and disclose standard terms, conditions, and rates for third-party access;
    - b. Require the regulatory authority to establish implementing regulations or other measures to provide for separation of accounts after notice and comment;
    - c. Clarify the obligations imposed by the Law on pipeline networks to respond to interconnection requests by competing gas suppliers;
    - d. Establish information firewalls, prohibit discriminatory treatment against specific third-party access users, and provide clear and explicit penalties and remedies for violations;
    - e. Implement a review of the effectiveness of behavioral regulations and ex-post monitoring; and
    - f. Provide for more structural methods of prohibiting unjust discriminatory treatment should behavioral regulations and ex-post monitoring prove insufficient.
  3. *Expanded Pipeline Infrastructure.*

- a. The U.S. Government encourages the Japanese Government to create an environment that is conducive to the construction of additional pipelines, including inter-regional “backbone” pipelines where cost effective, to enhance the flexibility of Japan’s gas transportation system. This would:
    - (1) Encourage a more economic distribution of natural gas in the country, making it more of a commodity and eventually reduce the cost to the end user; and
    - (2) Reduce the need for investment in “local” liquefied natural gas terminals, as fewer (but larger) terminals can handle deliveries for essentially the entire country.
  - b. The U.S. Government urges the Japanese Government to vigilantly monitor the decision-making process regarding effective use of existing pipelines in constructing new pipelines, to ensure that owners of existing pipelines do not use such regulation as a means of blocking or delaying needed construction of new lines.
4. *Rate Making.* The U.S. Government recommends that the Japanese Government promote more flexible, cost-based rate-making for transmission and distribution service, taking account of factors such as the length of transmission pipeline required to deliver gas to industrial firms and the density of distribution pipeline used to deliver gas to commercial firms and residential customers.
- B. Japan depends on imports of liquefied natural gas (LNG) to meet its gas requirements. As a result, and in contrast to a situation in countries with an extensive open access pipeline system in place, it is critical that true open access to LNG facilities is secured in a manner similar to third-party access to pipelines in order to create a truly competitive gas market. The U.S. Government recommends that the Japanese Government undertake the following steps that will help create secure, reliable access for all market participants to the gas pipeline system and LNG terminals.
1. The U.S. Government urges the Japanese Government to implement concrete and detailed ordinances/regulations to achieve the aim of non-discriminatory access that:
    - a. Require that LNG terminal owners create and make available to third parties information on terminal capacity, particularly excess capacity, in a timely manner;

- b. Require that LNG terminal owners create and make available to all applicants documents clearly detailing conditions and procedures for terminal use;
    - c. Require that LNG terminal owners provide written explanations to parties denied use of these terminals;
    - d. Establish guidelines for public disclosure of pipeline network and LNG terminal usage information; and
    - e. Clearly delineate government responsibilities and define the enforcement mechanism necessary to prevent LNG terminal owners from discriminating against potential users.
  - 2. Ownership of LNG terminals by vertically-integrated energy companies limits the likelihood that these incumbent companies will enter into terminal access contracts with potential rivals in a timely and efficient manner. The U.S. Government therefore urges the Japanese Government to implement additional measures, including through the adoption by METI of detailed and concrete regulations/ordinances, to impose fair and transparent access regulation on energy companies that fail to provide such access. Specifically, the U.S. Government urges METI to:
    - a. Establish a cost-of-service rate regime for each terminal that allocates costs and designs rates to account for terminalling (e.g., the storage of the LNG) and regasification costs;
    - b. Adopt a standardized tariff that details the terms and conditions of service from a LNG terminal should be devised, whereby such a tariff could deviate from the standard when necessary with allowance for variation for costs and technology as appropriate; and
    - c. Ensure the standardized tariff establishes open access procedures that permit third-parties to bid for capacity and a mechanism that determines winning bids (e.g., greatest net present value).
  - 3. New LNG terminals with connections to pipelines with third-party access should be open to third-party access.
  - 4. The U.S. Government urges that adequate staffing at METI is secured to undertake necessary regulatory and monitoring functions that ensure meaningful third-party access to LNG terminals is secured.
- C. The U.S. Government encourages Japan to continue to take necessary measures to further liberalize the gas sector, including:

1. Expansion of the scope of retail liberalization to approximately 50 percent of the market by including users with an annual demand of 100 thousand cubic meters and higher by 2007; and
2. Initiating at an early date consideration of when and how to liberalize gas retail sales to household and small commercial users with an annual demand of less than 100 thousand cubic meters.



## MEDICAL DEVICES AND PHARMACEUTICALS

- I. Medical Device and Pharmaceutical Pricing Reform and Related Issues.** Japan’s policy papers on the competitiveness of its pharmaceutical and medical device industries, known as “Visions,” recognize the value of innovation and the effects of pricing on innovative R&D investment. The Ministry of Health, Labor and Welfare (MHLW) has acknowledged that providing market incentives is critical to fostering competition in these industries, and has agreed to promote the speedy introduction of innovative products in the insurance system. The U.S. Government supports these efforts and urges Japan to:
- A. Accelerate implementation of the Visions.
  - B. Consult fully with industry, including U.S. industry, on pricing issues, and provide meaningful opportunities for input when considering changes to pricing rules or assessing their impact. Ensure that outside advisors consulted by MHLW afford industry, including U.S. industry, meaningful opportunities for input. Facilitate industry input and participation in the price-setting process by:
    - 1. Expanding representation of industry, including U.S. industry, in Chuikyo; and
    - 2. Allowing manufacturers to make presentations on their pricing requests at the initial product meeting of the Drug Pricing Organization and Special Organization for Insurance-covered Medical Materials.
  - C. Reform pricing rules to ensure an accurate assessment of the value of advanced medical devices and pharmaceuticals to Japan’s patients and healthcare system. Ensure that changes in pricing rules are consistent with MHLW’s recognition of the value of innovation. Consider the effect of regulatory approval delays and compliance with new Pharmaceutical Affairs Law (PAL) provisions on the cost of doing business in Japan when setting prices, and take the following steps:
    - 1. *Pharmaceuticals.*
      - a. Adopt a pricing method based on a manufacturer’s suggested reimbursement price as an alternative to the cost-calculation method;
      - b. Change the comparator pricing method to adjust the comparator drug’s price to offset previous price reductions;
      - c. Apply pricing premiums more fully;
      - d. Expand the sources and types of data used to select comparators and award premiums;

- e. Abolish the criteria of repricing based on market expansion;
- f. Ensure that the Foreign Price Adjustment rule for pharmaceuticals will not be altered in a way that would harm U.S. industry;
- g. Consider the need to recoup development costs for innovative products; and
- h. Adopt a new pricing method for biologics based on a manufacturer's suggested reimbursement price, in recognition of the unique characteristics of such products.

2. *Medical Devices.*

- a. Review the Foreign Price Adjustment rule for medical devices. Change the multiplication factors and other elements to reflect the unique characteristics that result in differences in cost structures in other markets;
- b. Consult fully with industry, including U.S. industry, on price data collection;
- c. Establish a team of government experts and representatives from industry, including U.S. industry, to enhance communication and develop recommendations to improve the R-zone process and C1 and C2 reimbursement categories;
- d. Offer a binding pre-submission consultation for C1 and C2 applications before a product review ends;
- e. Provide a provisional price for C1 products after approval when a price is requested or shortly afterward;
- f. Indicate any major questions or problems about a C1 or C2 pricing request within two weeks of the request;
- g. Speed decisions and increase predictability regarding C1 products by publishing clear criteria on C1 eligibility and premiums;
- h. Award C1 prices to products that significantly improve aspects such as treatment, diagnosis, or management of disease; and compliance; ease of use; recovery time; and long-term outcomes; and

- i. Adopt a value-based methodology for C2 products that assesses products individually, considering economic outcomes, quality of life, safety, efficacy, and other factors.
- D. Allow reimbursement of approved pharmaceuticals in preventive medicine.
- E. Extend market exclusivity for additional dosing regimens, combination therapies, or indications to provide a meaningful incentive to manufacturers during the reexamination period following the approval of these therapeutic options.
- F. Increase transparency and consultation with industry, including U.S. industry, regarding diagnostics (e.g., in-vitro diagnostics [IVD] and imaging equipment). Consider the value of diagnostics when determining diagnostic reimbursement pricing. For IVDs, ensure transparency in price data collection methods and implement a system to evaluate the clinical value of in-hospital tests. Establish an IVD subcommittee in Chuikyo.
- G. Take measures to ensure the adoption of innovative medical devices and pharmaceuticals under the Diagnosis Procedure Combination (DPC) system.
- H. Adopt treatment guidelines to ensure appropriate patient care and access to innovative medical devices.
- I. Consult closely with the pharmaceutical industry, including non-Japanese local firms, on the Intellectual Property Strategy Headquarters' consideration of proposals on strengthening intellectual property protection for pharmaceuticals.

**II. Medical Device and Pharmaceutical Regulatory Reform and Related Issues.** MHLW hopes to attain the Visions' goal of improving the competitiveness of Japan's medical device and pharmaceutical industries and markets by ensuring faster introduction of safer and more effective products. The Pharmaceuticals and Medical Devices Agency (PMDA), launched on April 1, 2004, is expected to increase the transparency, speed, and predictability of the application review process for approval and the post-marketing safety system. The U.S. Government urges Japan to:

- A. Comply with PMDA's performance goals by expediting reviews and approvals. For pharmaceuticals, add a new performance goal of completing 80 percent of consultations within 60 days of a consultation request. For medical devices, work toward exceeding the MOSS Agreement goals.
- B. Develop in consultation with industry, including U.S. industry, metrics to evaluate PMDA's performance that enhance the detail and transparency of PMDA's annual report on its compliance with the goals. Publish annual metrics that include:
  - 1. For pharmaceuticals, number and type of reviews (e.g., priority) and review times in terms of mean and median of administrative and total

time; number of Good Manufacturing Practice inspections, and time to complete such inspections; and

2. For medical devices, number of applications (total and approved), number of cycles per review of application documents, time spent on each step of evaluation, and time spent by the reviewer.

C. Take the following steps to improve transparency:

1. Hold more meetings between industry, including U.S. industry, and PMDA, MHLW, and any outside experts consulted by PMDA or MHLW. Consult fully with industry, including U.S. industry, on industry proposals.
2. Establish a mechanism in PMDA by which an applicant can, upon request, be informed about the status of its application. Reduce the time between a consultation request and the consultation meeting.
3. Ensure consistency between PMDA's pre-submission consultation and post-application evaluation by preparing a meeting-minutes memo of the pre-submission consultation for confirmation by both sides.
4. Inform firms when consulting outside advisors on issues (e.g., adverse events) affecting specific firms, and provide firms with substantive opportunities to interact with those advisors and safety officials. Choose experts with substantial and relevant first-hand clinical experience in the device or drug in question when seeking outside advisors.

D. Ensure that overseas audits or factory inspections do not delay approvals of new products. Clarify the processes and requirements for audits and inspections. For medical devices, accept as substantial evidence of compliance with pre-market requirements quality system certificates or inspection reports issued by recognized regulators and conformity assessment bodies. Reserve MHLW or PMDA medical device audits for special circumstances, such as when regulatory authorities or notified bodies have not issued such certificates or reports.

E. In developing requirements and guidance for medical devices, ensure that regulations produce benefits that justify costs. Enhance the use of published guidance in reviews and post-marketing surveillance. Adopt good guidance practices that give industry substantive opportunities to comment on proposed guidance before it is adopted. Ensure that regulations are based on sound science.

F. Make reviews more consistent by ensuring that outside experts in clinical-trial consultations are involved in reviews of the same product. Enhance PMDA reviewers' therapeutic expertise through continuing education and other means. Ensure that staff rotations are done in a way that enhances therapeutic expertise.

- G. Streamline medical device reviews by taking steps such as allowing simplification of submission material outlines (STEDs) for new products that are similar to existing devices; refraining from automatically evaluating as “new” a product whose classification changes from Class 1 to Class 2 or higher; and allowing changes in manufacturing processes or product designs to be made without regulatory approval if such changes do not affect safety or efficacy.
- H. In consultation with industry, evaluate the efficiency of the fast track and priority review processes and clarify these processes.
- I. Simplify the approval requirements for combination therapies and products.
- J. Establish performance goals for IVDs by April 2005 based on meaningful input from industry, including U.S. industry. Allow the IVD industry, including U.S. industry, to participate in a government study on guidelines for standard testing criteria by disease. Refrain from restricting the use of IVD tests that have received product approval when such use is requested by physicians.
- K. Work with industry, including U.S. industry, to clarify PMDA’s appeals processes for product reviews and safety-related activities.
- L. Implement a post-marketing safety system that better balances benefits and risks, and is based on sound science, statistics, and internationally harmonized methods. Develop a response mechanism to adverse event reports that is commensurate with the severity of the reported event and involves industry during the assessment of the report and subsequent actions. Resolve disputes on adverse events quickly and efficiently through an appeals process based on data and meaningful consultations between industry and MHLW and any experts consulted. For drugs, clarify the nature and use of MHLW and PMDA safety databases, including data mining analysis, and the interaction process between safety officials and product originators regarding the understanding of products’ safety profiles. For medical devices, incorporate the use of GHTF harmonized vigilance documents and allow quarterly summary reporting for inconsequential or well-known events.
- M. Adopt for medical devices international standards and guidance documents developed by organizations such as GHTF and ISO without substantive modification. Where international standards do not exist, develop standards based on internationally accepted performance criteria and avoid inappropriate design requirements. Ensure meaningful opportunities for input from industry, including U.S. industry, in the drafting process. Provide opportunities for public comment and notification to the WTO before adoption of standards.
- N. Accept overseas clinical data where compliance with Good Clinical Practices has been demonstrated.

- O. Continue meaningful consultations with industry, including U.S. industry, regarding the replacement of the In-Country Caretaker system by the Market Authorization License system. Adopt measures to prevent the withdrawal of manufacturers from the market because of the change in systems.

**III. Blood Products.** The U.S. Government urges Japan to:

- A. Consult fully with industry, including U.S. industry, on regulatory and reimbursement pricing matters related to blood products. Fulfill the commitment in the 2004 Report to the Leaders to bring together in CY2004 all interested parties to discuss concerns relevant to blood products such as patient care, declining demand, and other issues.
- B. Apply policies and regulations in a fair and transparent manner. Ensure that the Supply and Demand Plan's implementation does not discriminate against foreign products and is fully consistent with Japan's international trade obligations.

**IV. Nutritional Supplements Liberalization.** The U.S. Government urges Japan to:

- A. Allow sales in Japan of ingredients and excipients produced and manufactured in Japan for export to the United States.
- B. Allow the use of educational and informational statements on labels and in advertising for nutritional supplements.
- C. Reduce duties for nutritional supplements to the same level as duties for pharmaceuticals containing the same ingredients.
- D. Increase participation in nutrition-related Codex activities to help establish international guidelines and standards fostering international trade.
- E. Base potency limits on risk assessments.

## FINANCIAL SERVICES

- I. Specific Measures.** The United States would welcome regulatory reform in Japan in the following areas at the earliest possible date:
- A. Putting foreign bank branches on an equal footing with domestic banks by allowing them to engage in trust and banking businesses concurrently, pursuant to Article 1, paragraph 1 of the Concurrent Operation Law.
  - B. Harmonizing the regulatory framework governing investment advisory and investment trust management activities and eliminating inconsistencies or duplication.
  - C. Allowing mergers and reducing obstacles to the early termination of investment trusts, in order to permit investment managers to combine and diversify investments, which would result in a reduction of both risk and cost to investors.
  - D. Ensuring meaningful disclosure to consumers and protecting consumer privacy by allowing lenders to satisfy disclosure requirements under the Money Lending Business Law by electronic notice where customers have consented to such disclosure after clear and conspicuous notice from lenders. Vigorously enforcing existing regulations to protect consumers from abusive practices by lenders and debt collectors.
  - E. Increasing the Defined Contribution (DC) pension plan limits to an even higher level, which would make DC pension plans a real and viable retirement savings option for employees and a true alternative to Defined Benefit (DB) pension plans for employees of companies that offer an option of DB or DC plans. Permitting employees to match the contributions of their employers.
- II. Transparency.** To improve transparency in financial sector regulatory and supervisory practice, the United States would welcome measures in the following areas at the earliest possible date:
- A. The U.S. Government recommends that Japan's Financial Services Agency (FSA) build on recent progress in the FSA's no-action letter system as a means of expanding the body of written interpretations of Japanese financial laws and regulations. Such written interpretations are essential to reducing uncertainty as to what financial products and services are prohibited under Japanese law, thereby increasing the scope for innovation by financial services providers. To that end, the U.S. Government recommends that the FSA take further steps to enhance the effectiveness of its no-action letter system, drawing upon the recommendations laid out in sub-section VIII of the "Transparency and Other Government Practices" section of this report, and:

1. Establish a “frequently-asked-questions” page on the FSA web site, or some equivalent vehicle to provide written responses to oral requests received for interpretations of Japanese financial laws and regulations.
  2. Increase the issuance of and clarify the language used in FSA Guidelines as a means of providing written interpretations of Japanese financial law, either in response to oral and written requests or proactively on the FSA’s part.
- B. The U.S. Government welcomes the FSA’s efforts to promote transparency by providing a period of public comment on its Guidelines relating to the Law on the Protection of Personal Information. The U.S. Government urges the FSA to carefully consider the comments and concerns of financial firms and associations and create guidelines that protect personal information in a manner consistent with established privacy protection systems, without impeding the ability of financial firms to effectively provide innovative products and services to Japanese consumers.
- C. The U.S. Government welcomes recent progress in enhancing the transparency of FSA Rulemaking Procedures and the implementation of new or revised FSA regulations and ordinances, and would welcome further efforts to solicit input from affected parties. Such steps would include increased use of public hearings and continued reliance on the Public Comment process under the Administrative Procedures Law in connection with existing and new regulations or guidelines.
- D. As a complement to self-regulatory organizations, the United States requests that Japanese financial authorities continue to work closely with private sector financial industry associations, such as the American Chamber of Commerce in Japan and the International Bankers Association, that fully represent the views and the expertise of their members.



## COMPETITION POLICY

- I. Strengthening the Effectiveness of Antimonopoly Enforcement.** The successful protection and promotion of competition in the Japanese economy depends on a strong Antimonopoly Act (AMA) that establishes high sanctions sufficient to constitute an effective deterrent to anti-competitive behavior and provides the Japan Fair Trade Commission (JFTC) with the most modern investigatory tools to uncover anti-competitive practices. To ensure that AMA enforcement is most effective, the United States urges Japan to:
- A. Strengthen the Surcharge System.
    - 1. Double surcharge rates for all categories of violators;
    - 2. Impose significantly higher than normal surcharge rate on companies that repeat cartel or bid rigging activities within ten years;
    - 3. Apply surcharges to all conspiratorial sales of a company occurring during the full term of a cartel or bid rigging conspiracy, or at least during a term significantly longer than the current three year maximum; and
    - 4. Expand the scope of activities subject to surcharge orders to include collusive agreements restraining output, market share or customers and illegal buying cartels.
  - B. Introduce a Corporate Leniency Program.
    - 1. Eliminate surcharges for the first company that discloses to JFTC the existence of a cartel prior to a JFTC investigation, and excludes that company, and any of its employees that provide full cooperation to JFTC, from any criminal accusation related to that cartel; and
    - 2. Reduce the surcharge amount for only one or two additional companies who provide crucial assistance to JFTC's investigation.
  - C. Increase JFTC's Investigation Effectiveness.
    - 1. Grant JFTC compulsory investigative powers for purposes of filing criminal accusations;
    - 2. Strengthen penalties against companies and their employees that obstruct JFTC investigations;
    - 3. Extend the statute of limitations for JFTC to issue cease and desist orders to three years after termination of the unlawful conduct; and

4. Give JFTC investigation priority to conduct that clearly harms the competitive process.
- D. Improve Criminal Sentencing. With the aim of improving sentencing for criminal AMA violations, have the Ministry of Justice (MOJ) or other appropriate government entity encourage the Supreme Court to initiate a study of sentences of individuals convicted of violations of the AMA to determine whether sentences are in accord with international practice and the underlying goals of the AMA.
- E. Reduce AMA Exemptions. With the aim of ensuring that AMA exemptions are as limited as possible, have the JFTC initiate a review of AMA exemptions to determine whether any can be further narrowed or eliminated.
- F. Increase JFTC Resources.
1. Increase the number of staff with post-graduate economics training, including through sending staff for advanced economics degrees and employing outside economists as temporary JFTC staff, or as consultants, on specific investigatory matters; and
  2. Continue to increase the staff and budget of JFTC substantially and steadily.
- G. Promote AMA Compliance.
1. Increase JFTC's efforts to work with business organizations and trade associations to encourage member companies to adopt effective programs that ensure that employees do not engage in practices that violate the AMA; and
  2. Continue to issue new AMA guidelines, or update or expand existing ones, to assist companies in complying with the AMA.

**II. Increasing Procedural Fairness of JFTC Enforcement Activities.** The JFTC's authority and credibility in the business community will be best assured if the business community has confidence that enforcement actions are fairly applied. In order to improve confidence in the JFTC's enforcement activities, the United States recommends that Japan:

- A. Strengthen confidence in hearing procedures by increasing the number of judges and lawyers acting as hearing examiners; and
- B. Allow companies that may be the subject of a proposed public warning by JFTC to make arguments as to why such a warning should not be issued.

**III. Addressing Bid Rigging Effectively.** Bid rigging continues to a significant problem in the Japanese economy. Bid rigging undermines necessary restructuring and harms consumers, taxpayers and the most efficient bidders. Government-led bid rigging is particularly pernicious since government officials are directly involved in flouting the law and undermining the creation of a culture of competition in Japan. In order to effectively address bid rigging, the United States urges Japan to:

A. Strengthen Measures Against Government-led Bid Rigging.

1. Set out stronger sanctions, including new criminal provisions as necessary, against government officials who instigate or attempt to instigate bid rigging on government projects; and
2. Ensure that JFTC reports to the Public Prosecutor's Office and to the relevant procuring agency the name of any government official it suspects instigated, attempted to instigate or was otherwise involved in bid rigging activities, together with the information upon which the JFTC suspicion's are based.

B. Introduce Administrative Leniency Program. With the aim of encouraging voluntary reporting of bid rigging activities, examine the merits of adopting a program under which the Ministry of Land, Infrastructure and Transport (MLIT) and other appropriate government entities:

1. Exempt from administrative sanctions, including suspension of designation, the first company that comes forward to report to the relevant ministry or to the JFTC the existence of bid rigging; and
2. Take adequate measures to protect the identity of the leniency applicant from disclosure.

C. Address Bid Rigging at the Local Government Level. With the aim of combating bid rigging at the local government level, have the Ministry of Internal Affairs and Communications (MIC) take additional measures that will strengthen efforts to reduce bid rigging on local government contracts, including adopting a policy of conveying to the JFTC information indicating a suspicion of bid rigging.

D. Improve Transparency in Sanctions. Ensure that MLIT, MIC and other relevant government agencies annually publish a report listing each company that was determined to have engaged in bid rigging during the previous year, and specifying for each such company the administrative sanctions that were imposed, and the amount each company paid to compensate the government for its damages from the bid rigging activities.

E. Reform the Bidding System.

1. Examine the adoption of new bidding procedures that will make bid rigging more difficult; and
2. Seek public comment under the Public Comment Procedures on any proposed new bidding procedures for such purposes.

**IV. Promoting Competition Throughout the Economy.** Competition can be best promoted, not just through AMA enforcement actions, but also through advocating to other government agencies the adoption of pro-competitive regulations and measures. In order to maximize the promotion of competition through the Japanese economy, the United States urges Japan to:

A. Conduct Privatization in Pro-Competitive Manner.

1. Encourage Japanese Government entities tasked with proposing or supervising privatization efforts, including with regard to privatization of Japan Post, to seek JFTC's views on how to proceed with privatization in the most pro-competitive manner; and
2. Ensure that JFTC diligently monitors the activities of government-owned entities in the process of privatization to ensure that they do not engage in anti-competitive exclusionary behavior.

B. Promote Competition in Regulatory Reform.

1. Ensure that JFTC actively participates in study groups convened by regulating agencies considering sectoral reforms; and
2. Have JFTC actively assist the work of the Council for the Promotion of Regulatory Reform by, among other things, conveying JFTC's analyses and recommendations on how to promote competition in regulated sectors.

## TRANSPARENCY AND OTHER GOVERNMENT PRACTICES

- I. Public Comment Procedures.** While Japan's Public Comment Procedures (PCP) have been in place since 1999, implementation of those procedures often fails to support the PCP's central purpose of promoting transparency and a fairer and more open rule-making system. The Ministry of Internal Affairs and Communication (MIC) released another annual survey of PCP implementation in August of 2004, which demonstrated continuing problems with the PCP. That survey showed that in FY2003, roughly half of the public comment periods for regulatory revisions requiring Cabinet decisions were shorter than 28 days; less than one percent of these comment periods were closer to a more reasonable 60-day period. Additionally, the survey showed that public comments were not incorporated into a vast majority of the final regulations. The United States urges Japan to eliminate inadequacies in PCP implementation so as to make it an effective and meaningful regulatory mechanism. The United States therefore welcomes the Cabinet's endorsement of the Three-Year Plan for Promotion of Regulatory Reform, which includes studying proposals in FY2004 to improve the PCP. The United States recommends that as Japan considers revising the PCP, it does so in a manner that would:
- A. Standardize a 60-day comment period, or at a minimum, require the use of a minimum 30-day comment period, except in urgent cases;
  - B. Require Ministries and Agencies to state publicly why it is necessary to shorten the comment period when such cases arise;
  - C. Require the publication of draft regulations at the earliest possible time, to allow interested parties sufficient time to analyze issues and prepare meaningful public comments;
  - D. Ensure Ministries and Agencies provide sufficient time between the closing of a comment period and finalizing regulations so that comments can be incorporated where appropriate;
  - E. Establish a more effective centralized system that would allow the public to easily find solicitations and results of public comments from all Ministries and Agencies, (whether or not they are covered by the PCP) including those by *shingikai*, *kenkyukai*, *benkyokai* and other study groups;
  - F. Increase opportunities for foreign industry associations to present their views before *shingikai*, either as experts or as interested parties;
  - G. Eliminate the practice of placing overly rigid parameters on the public comment submissions, such as substantially limiting page length, requiring an 80-character summary, and other impediments that undermine the spirit of the PCP;
  - H. Require that all proposed rule-making by government-established or authorized self-regulatory organizations be made available for public comment, and

comments received should be reflected in final regulations, to the extent appropriate;

- I. Require Ministries and Agencies to make public and post on their websites the complete texts of submitted comments as well as official counter-comments and the sources, indicating how the comments were incorporated, or if not incorporated, the reasons why; and
- J. Incorporate the PCP into the Administrative Procedures Law, which would strengthen it from being a guideline to being a law.

**II. APEC Transparency Standards.** APEC leaders have agreed to a package of transparency standards for the range of trade and investment areas. The United States and Japan have worked closely to create these standards. Accordingly, the United States and Japan should work jointly to achieve full implementation of the APEC Transparency Standards in the domestic legal regimes of countries in the Asia-Pacific region.

**III. Special Zones for Structural Reform.** The U.S. Government continues to support regulatory reform in Japan through the establishment of the Special Zones for Structural Reform. The United States is pleased to note that since the approval of the first zones in April 2003 the total number has grown to 386, with 26 deregulation measures approved for application nationwide by the Cabinet in September 2004.

- A. To ensure that this initiative continues to help revitalize local economies throughout Japan, the United States recommends that:
  - 1. Transparency remain a centerpiece of all aspects of the zones initiative;
  - 2. A focus be placed on expanding market-entry opportunities, with domestic and foreign companies alike having non-discriminatory access to operate in the zones;
  - 3. The Special Zones Headquarters continue to place a priority on expeditious nationwide application of successful measures;
  - 4. The Zones Headquarters continue to work with U.S. and other foreign companies to submit zone ideas, participate in existing zones, and participate in the zones process at every stage; and
  - 5. Foreign participation be encouraged by publishing in English on the Internet a comprehensive list of current zones, progress on zone applications, and updated zone information.
- B. The United States has been encouraging participation by U.S. entities in the zones initiative and requests that the Japanese Government give careful consideration to zone proposals that involve U.S. participation, such as:

1. Zone proposals to reduce academic and administrative regulatory burdens on foreign university branch campuses;
2. A zone proposal for importing chipping potatoes, which would benefit Japanese manufacturers and consumers by ensuring a steady supply of chipping potatoes year-round. Japanese chip manufacturers currently must decrease operations during the spring season, when domestic potatoes suitable for chipping are unavailable. This particular proposal, based on a protocol for shipping directly to the manufacturers under strictly controlled conditions, would fully alleviate plant health concerns; and
3. Any future proposals to allow zones for commercial delivery of advanced medical treatments, as well as other future zone proposals in the health care services sector.

**IV. Public Input into the Development of Legislation.** The United States commends the growing frequency of ministries and agencies opting to solicit public input into draft legislation during its development and before Diet submission. The United States encourages Japan's ministries and agencies to accelerate the practice of providing greater opportunities to comment on legislation in the early stages of its formation. Two specific examples of the need for providing sufficient public input in this regard are:

- A. Life Insurance Policyholder Protection Corporation. Working Group discussions of the Financial System Council (FSC) began in early 2004 on issues related to the reform of the Life Insurance Policyholder Protection Corporation (Life PPC) in advance of the expiration of the current financing structure in March 2006. The United States urges Japan to take prompt action to ensure that subsequent legislation is enacted to establish a more efficient, sustainable safety net system before the current system expires. A viable safety net system is essential to ensuring public confidence in the industry as well as the financial health and operations of both domestic and foreign life insurance companies, and substantial changes to that system will have a tremendous impact on the industry and consumers alike. Therefore, the United States also urges the Japanese Government to fully utilize and implement the Public Comment Procedures and ensure that the insurance industry (both domestic and foreign) and all interested parties are provided meaningful opportunities to be informed of, comment on, and exchange views with officials on proposed amendments to the Insurance Business Law, the Life PPC reform legislation or other existing laws and regulations related to the Life PPC prior to their implementation and/or submission to the Diet. These opportunities include actively contributing to the deliberations on reforming the Life PPC, including to those of the FSC Working Group or other groups which might be convened by the Japanese Government to address Life PPC reforms.

B. Non-Life PPC. In the event legislation is considered to address funding of the Non-Life PPC, the U.S. Government urges the Japanese Government to follow a similar approach as recommended immediately above in section A.

**V. Postal Financial Institutions.** The U.S. Government continues to share concerns voiced by Nippon Keidanren and others about the effect of the postal financial institutions -- postal savings (*yucho*) and postal insurance (*kampo*) -- on the efficient operation of Japan's financial markets.

A. Transparency. With regard to the formulation of proposed amendments to laws related to *kampo* products and distribution or origination by Japan Post of non-principal-guaranteed *yucho* investment products, the United States urges relevant parties in the Government of Japan to take steps to sufficiently inform and seek input from the public (including foreign insurers) on all aspects that may affect private sector operations in the relevant sectors. This includes providing the insurance industry and other private sector interested parties (both domestic and foreign) meaningful opportunities to comment on and exchange views with relevant Japanese officials on:

1. Proposed plans and draft legislation prior to their submission to the Diet; and
2. Draft guidelines and other regulatory measures prior to their implementation, with full utilization and implementation of the Public Comment Procedures.

B. Same Standards and Curb Expansion. The United States urges that a fully level playing field be achieved between the postal financial institutions and their private sector competitors, in accordance with measures outlined in II.A.1. of the Privatization Chapter. Until a fully level playing field is achieved, the United States also urges Japan to prohibit the postal financial institutions from underwriting any new or altered insurance products that the private sector can provide, or originating any new non-principal-guaranteed investment products.

**VI. Bank Sales of Insurance.** Liberalization of the banks sales channel for insurance products will expand consumer choice and access in a manner consistent with Japan's "Big Bang" reforms. The United States calls on Japan to adopt the following steps:

- A. Implement an across-the-board liberalization of the bank sales channel, no later than within the three-year period recommended by the Financial System Council's Insurance Working Group in March 2004 for full liberalization to be achieved in principle.
- B. Ensure that any partial liberalization steps taken within the three year period, as recommended by the Insurance Working Group, are undertaken in a balanced, fair manner that do not disadvantage U.S. companies.



- C. Abolish or revise Article 211 of the Insurance Business Law Enforcement Regulations at an early date in a manner that is consistent with sales of insurance products through other channels and that enables banks selling insurance to utilize all available methods of distribution.
- D. Ensure transparency by providing interested parties (including foreign parties) meaningful opportunities to exchange views with relevant officials on bank sales of insurance and Article 211 as well as by fully utilizing Public Comment Procedures.

**VII. Insurance Cooperatives.** Insurance cooperatives (*kyosai*) provide a range of insurance products that compete directly with the private sector and occupy substantial market share in the Japanese insurance market. Some *kyosai* are regulated by government agencies other than the insurance regulator, the FSA. Some *kyosai* are not regulated at all. The lack of a regulatory regime for unregulated *kyosai* and weaker regulatory regimes for other *kyosai* undermine the ability of the Government of Japan to provide companies and policyholders with a sound, transparent regulatory environment, and afford the *kyosai* significant business, regulatory and tax advantages over their private sector competitors. The United States recommends Japan take the following steps:

- A. Create a level playing field between *kyosai* and their private sector competitors, by subjecting all *kyosai* to the same laws, level of taxation, safety net contribution requirements, reserve requirements, standards and regulatory oversight as their private sector counterparts.
- B. The United States is encouraged that deliberations on unregulated *kyosai* are now underway within the Insurance Working Group of the Financial Systems Council, and urges that a similar review of regulated *kyosai* is launched at an early date. The United States also urges that these discussions, as well as within relevant ministries and agencies, are undertaken in an open and transparent manner, with opportunities for interested parties (including foreign parties) to actively contribute to the deliberations and exchange views with relevant officials.

**VIII. No Action Letters.** The United States recommends that Japan take further steps to enhance the effectiveness and increase the usage of Japan's no-action letter system, which provides regulated firms with an opportunity to seek clarification of an administrative agency's interpretation of laws and regulations. Measures that would contribute to a more effective no-action letter system include:

- A. Giving Japan's no-action letter system, which was established under a Cabinet Decision, the force of law by incorporating its requirements into the Administrative Procedures Law (APL).
- B. As an interim step, providing by Cabinet Decision more detailed government-wide guidelines to administrative agencies as to the requirements governing the agencies' individual no-action letter systems, and setting a

timetable for those agencies to set up their no-action letter systems. Specific steps should include:

1. Establishing a single “window” at each agency to receive no-action letter requests.
  2. Adopting measures to promote more active use of the no-action letter system, including:
    - a. Outreach efforts by administrative agencies to inform firms in regulated industries that they can seek clarification of Japan’s laws and regulations via the agency’s no-action letter system;
    - b. Announcing that groups of firms and/or industry associations can submit NAL requests on behalf of specific firms; and
    - c. Establishing internal systems to encourage agency staff to actively solicit no-action letters from individual firms and other interested parties that seek informal oral interpretations of laws and regulations on issues that are matters of settled policy.
- C. Establishing both government-wide and agency-specific fora for seeking private sector input as to how to improve the no-action letter systems of the various government administrative agencies.

**IX. Government Practices Relating to Agriculture.** In its recent comprehensive, independent evaluation of Japan’s plant quarantine program, the Ministry of Agriculture, Forestry, and Fisheries (MAFF) addressed the development of international standards based on criteria set forth in the WTO SPS agreement, as well as the need for countries to harmonize their plant quarantine measures with these international standards in the absence of technical justifications to the contrary. The evaluation affirmed that Japan is “aware of the need to apply plant quarantine measures based on international standard(s).” The United States believes, however, that Japan has not adhered to or adopted the international standards in some cases. For example, Japan may not have adequately considered alternatives to pesticide treatments for mitigation, such as systems approaches involving numerous actions that, when applied cumulatively, have been demonstrated to have nearly the same effect as fumigation. The U.S. Government encourages Japan to adopt a more internationally accepted plant quarantine system based on the International Plant Protection Convention (IPPC) standards for official control, the science of risk analysis, and the application of the least restrictive measures to ensure safe trade.

- A. Official Control of Regulated Pests. The United States urges Japan to broaden its concept of non-quarantine pests to ensure non-discriminatory treatment of imported agricultural commodities. For example, under current practice, imported products such as lettuce often must be fumigated (needlessly and at great expense)

to avoid delays in entry to the market, while domestically produced commodities with the same pests can be moved freely throughout Japan. To address inconsistencies between current practice and established international definitions and guidelines, the United States urges MAFF to base its plant quarantine measures related to regulated quarantine pests and official control on IPPC definitions and guidelines, including but not limited to the following principles:

1. A quarantine pest that is present in the importing country cannot be widely distributed and must be under official control;
2. Official control is defined as the active enforcement of mandatory phytosanitary regulations and the application of mandatory phytosanitary procedures with the objective of eradication or containment of quarantine pests or for the management of regulated non-quarantine pests;
3. Official control includes: eradication or containment in the infested area(s); surveillance in the endangered area(s); movement controls into the protected area(s);
4. Official control requirements should be non-discriminatory. Requirements for imports should not be more stringent than domestic requirements for the same pest;
5. Official control requirements should be transparent. Import and domestic requirements should be documented and made available, on request; and
6. Domestic and import requirements should be based on technical justification (risk assessment) and should result in non-discriminatory risk management.

B. Pest Risk Assessment and Management. The United States urges Japan to ensure that its phytosanitary quarantine measures are supported by pest risk assessments that consider risk-appropriate alternatives to existing quarantine regulations and provide sufficient scientific evidence to support the perceived risk. When conducting risk assessments, the United States asks that MAFF incorporate International Plant Protection Convention (IPPC) guidelines and standards regarding risk assessment, including but not limited to the following:

1. Pest risk assessments should include an assessment of the likelihood of pest entry, establishment, and spread; and
2. The entire risk assessment process, from initiation of the pest risk assessment through risk management options selected, should be transparent, well documented, and available upon request.

## PRIVATIZATION

**I. Privatization of Public Corporations.** The United States continues to take interest in Prime Minister Koizumi's efforts to restructure and privatize Japan's public corporations. The United States also recognizes that, if implemented vigorously, this reform effort can have a major impact on the Japanese economy, stimulating competition and leading to a more productive use of resources. As reform of the public corporations advances, the United States continues to urge Japan to:

- A. Conduct the restructuring and privatization in a transparent manner; and
- B. Ensure that domestic and foreign private sector entities that will or may be affected by the reform have meaningful opportunities to provide input, such as through use of the Public Comment Procedures.

**II. Privatization of Japan Post.** Privatization of Japan Post must be ambitious and market-oriented to achieve maximum economic benefits for the Japanese economy. A truly market-oriented approach must include the establishment of undistorted competition in Japan's insurance, banking, and express delivery markets through, among other measures, the elimination of all advantages accorded to Japan Post over its private sector competitors. These advantages have long been of concern to U.S. and Japanese companies alike. The Council on Economic and Fiscal Policy (CEFP) took an important step in its September 10 "Basic Policy on the Privatization of the Japan Post" by recognizing the importance of establishing "equal footing" as well as equalizing the "competitive conditions" between Japan Post and private companies. The CEFP report also identifies specific measures with regard to same tax and safety net obligations and the termination of government guarantees on products for the postal insurance and savings businesses to be taken from the start of privatization in 2007. The U.S. Government welcomes these specific recommendations and urges their inclusion in legislation to privatize Japan Post.

A. Postal Insurance and Postal Savings. In order for the privatization of Japan Post to fully achieve the CEFP's call for "equal footing" with the private sector as well as to bring about fair competition in Japan's insurance and banking sectors, the United States urges Japan to take the following measures:

- 1. Establish a truly level playing field with private sector companies, including:
  - a. Subjecting the postal insurance and savings businesses to the same laws, regulations, tax requirements, reserve requirements, standards, and regulatory supervision as the private sector;
  - b. Taking sufficient steps to avoid public perceptions of implicit government guarantees on new postal insurance and postal savings

products, especially until the full divestiture of government shares in the postal insurance and savings businesses is complete;

- c. Implementing adequate measures, including full accounting transparency, among the new postal insurance, postal savings, and other affiliated businesses to ensure their transactions are arms-length and eliminate the potential for cross-subsidization among Japan Post's financial and non-financial businesses; and
  - d. Taking appropriate measures, including rigorous enforcement of the Antimonopoly Act, to ensure that the postal insurance and savings businesses do not use their market power to distort competition.
2. Implement a moratorium on the introduction of new lending services, new or altered insurance products underwritten by the postal insurance business, and the origination of non-principal-guaranteed investment products by the postal savings business until after a truly level playing field (as recommended immediately above) has been achieved, and at that point ensure that such products and services are introduced in a balanced manner.
  3. As the Japanese Government moves forward with plans to allow Japan Post to distribute privately-originated non-principal-guaranteed investment products, ensure that the selection of such products is conducted in a fair and transparent manner.
  4. Ensure that any selection of privately-originated insurance products to be distributed through Japan Post is conducted in a fair and transparent manner.
  5. Ensure no new advantages are accorded to the postal insurance and savings businesses as a result of the privatization process.
  6. Create an independent committee to review on a regular basis the conditions of competition between postal insurance and savings businesses with private sector companies, with the goal of ensuring that equal conditions are maintained throughout the privatization process.
- B. Express Delivery Services. In order to foster fair competition between Japan Post and express delivery carriers, the United States urges Japan to take the following measures:
1. *Independent Regulator*. Ensure that the regulatory authority for postal matters is separate and independent from Japan Post, and has sufficient

authority to ensure that Japan Post, or any entity it controls, does not operate in an anti-competitive manner.

2. *Non-Discriminatory Treatment.* Ensure as appropriate that government policies do not accord a supplier of a competitive service special benefits that modify the terms of competition, such as exemption from taxes and other fees, special treatment by government agencies in the transport of goods, and exemption from the cost of Customs operations.
3. *Cross-Subsidization.* Implement controls to prevent anti-competitive cross-subsidization of competitive services with revenues gained from the supply of universal services. One such control could be to ensure that accounting for Japan Post and all its related companies are separate, independent, and fully transparent.

C. Transparency. The United States urges that continued transparency of the Japan Post privatization process is secured, whereby:

1. Meaningful opportunities are made available upon request to interested private sector parties (including foreign parties) to exchange views with officials of relevant ministries and agencies, including the Ministry of Internal Affairs and Communications, the Office for Privatization of Japan Post, and the Financial Services Agency, during the preparatory and transitional phases of Japan Post privatization on issues that may impact the private sector.
2. Meaningful opportunities are provided to interested private sector parties (including foreign parties) to actively contribute to deliberations by committees or components of such committees convened by the Government of Japan on issues relating to the preparatory and transitional phases of Japan Post privatization that may impact the private sector.
3. Public Comment Procedures are fully utilized, including for the preparation of implementing regulations and ordinances related to privatization, and that comments are factored into final decisions.

## LEGAL SYSTEMS REFORM

- I. Ensuring Freedom of Association for Foreign Lawyers.** The 2003 amendments to the Special Measures Law Concerning the Handling of Legal Business by Foreign Lawyers were an important step toward providing freedom of association between foreign legal consultants (*gaiben*) and Japanese lawyers (*bengoshi*). The freedom of association provided by the 2003 amendments will, when the amendments become effective and if they are implemented in a manner consistent with the letter and spirit of the law, contribute greatly to the ability of Japanese consumers to obtain integrated legal services in a timely and efficient manner. For that purpose, the United States recommends that Japan:
- A. Fully implement the 2003 amendments by April 1, 2005;
  - B. Take necessary action so that the implementing rules and regulations of the Japan Federation of Bar Associations (*Nichibenren*) are consistent with both the letter and spirit of the 2003 amendments, particularly by ensuring that:
    - 1. *Nichibenren*'s rules and regulations are not applied in a way that constrains the ability of a *gaiben* partner who employs a *gaiben* associate with different scope of practice from accepting legal matters to be handled by that *gaiben* associate;
    - 2. Applicable rules and regulations related to ethics and confidentiality are applied equally to *bengoshi* and *gaiben*, regardless of whether they are members of a joint enterprise (*gaikokuho kyodo jigyo*) or a domestic law firm; and
    - 3. Required explanations to clients on the authority and scope of legal business for each *bengoshi* and *gaiben* are consistent with modern international practice and are not unreasonably burdensome.
- II. Permitting Professional Corporations and Branches.** *Gaiben* should have the same substantive rights as *bengoshi*, including the ability to form professional corporations and to establish branch offices. The United States welcomes the fact that the Ministry of Justice (MOJ) is studying whether to permit *gaiben* to form professional corporations. The United States urges Japan to:
- A. Complete the MOJ study by the end of JFY2004, with a view to permitting *gaiben* to form professional corporations on the same basis and with the same benefits as *bengoshi* professional corporations, including the ability to establish branch offices; and
  - B. Allow foreign law firms and their *gaiben* partners in Japan to establish branches in Japan without being required to form a separate Japanese legal professional corporation.

**III. Easing Minimum Qualification Criteria for *Gaiben*.** In order to encourage foreign lawyers with a long-term interest in Japan to seek qualification as a *gaiben*, the United States urges Japan to count all of the time that foreign lawyers spend practicing the law of their home jurisdiction in Japan toward the three-year experience requirement.

**IV. Promoting Alternative Dispute Resolution.** Japan has recognized that Alternative Dispute Resolution (ADR) mechanisms can play an important role in helping individuals and businesses resolve disputes in an efficient and economical manner, and is studying measures to strengthen and revitalize ADR in Japan. The United States welcomes Japan's commitment to create a flexible and open legal environment that facilitates the development of ADR services in Japan. For those purposes, the United States urges Japan to:

A. Adopt a Basic Framework for ADR. With the aim of creating a flexible and open legal environment for ADR, ensure that any legal regime established for ADR:

1. Is consistent with international norms and practice, including the UNCITRAL Model Law on International Commercial Conciliation;
2. Permits *gaiben* and foreign lawyers traveling to Japan to represent parties in all forms of ADR processes in which international aspects exist to the same extent as they are currently permitted with respect to arbitration proceedings;
3. Allows ADR processes to be flexibly tailored to particular circumstances by allowing the parties to ADR to agree, as a general matter, upon the rules, process and standards to be applied; and
4. Ensures that *ad hoc* (self-administered) international arbitration and mediation, and international institutions such as the International Chamber of Commerce, American Arbitration Association, London Court of International Arbitration and other such institutions, are clearly legitimate and proper under Japanese law and can continue to operate in Japan without the necessity for licensing by the Japanese Government or its designees.

B. Allow Non-Lawyers to Act as Neutrals in ADR Processes.

1. Clarify through new legislation that dispute resolution institutions, *gaiben* and non-lawyers acting as neutrals for pay in arbitration, mediation, conciliation and other ADR processes are not considered to be practicing law and are not in violation of Article 72 of the Lawyers Law or, where applicable, the Foreign Lawyers Law; and



2. Ensure that there is no requirement, as a general matter, that ADR processes in which non-lawyers are acting as neutrals, or the non-lawyers themselves, be supervised by *bengoshi*.
- C. Limit any ADR Licensing Regime. With the aim of preventing the creation of impediments to ADR processes, ensure that any ADR licensing system that may be established:
1. Does not apply to arbitration services;
  2. Is completely voluntary;
  3. Makes clear there should be no implication that non-licensed organizations or entrepreneurs providing ADR services for fees are in contravention of the Lawyers Law or that the resolution of disputes that results from the ADR services provided by non-licensed organizations or entrepreneurs is subject to legal challenge because of the non-licensed status of the ADR providers;
  4. Is open to foreign individuals and organizations on the same basis as for Japanese nationals and organizations; and
  5. Establishes procedures and standards for licensing, and any post-licensing reporting requirements, that are reasonable and not unduly burdensome.

## COMMERCIAL LAW

**I. Adoption of Modern Merger Techniques.** The availability of modern merger techniques in Japan will promote the revitalization of Japan's economy by encouraging corporate restructuring and increased investment. The United States welcomes the efforts of Japan to modernize Japan's corporate law, including through the introduction of modern merger techniques, and to examine other measures to facilitate corporate restructuring and investment. To accomplish those objectives, the United States urges Japan to:

- A. Submit legislation in the next regular session of the Diet that introduces modern merger techniques into Japan's corporate law, including by:
  - 1. Introducing flexibility in merger currency to the extent necessary to permit the use of triangular mergers, cash mergers, and share exchanges using foreign shares; and
  - 2. Permitting short form (squeeze-out) mergers.
- B. Take other measures to facilitate mergers and acquisitions and corporate restructuring in Japan, including providing for appropriate tax treatment of modern merger techniques in line with the Japan Investment Council decision of March 2003 and the August 17 report of the Cabinet Office Economic Strategy Research Institute's study group on facilitating mergers and acquisitions, while avoiding imposing specific conditions on the availability of such measures that might unduly limit the usefulness of new M&A tools in Japan.

**II. Promoting Shareholder Value through Active Proxy Voting.** The active exercise of shareholder rights by large institutional investors is crucial to the development of good corporate governance systems in Japan that will improve corporate performance. The United States welcomes the measures already taken by Japan to encourage active proxy voting by pension funds and mutual funds. In order to further improve investment returns through effective corporate governance, the United States urges Japan to:

- A. Promote Sound Proxy Voting Policies by Pension Funds.
  - 1. Have the Ministry of Health, Labor and Welfare make public the proxy voting policies of each of its fund managers; and
  - 2. Begin a study of whether a fiduciary duty on private fund managers to exercise proxy votes for the benefit of their beneficiaries should be established, in light of international trends and the needs to protect the interests of Japanese pension beneficiaries.
- B. Encourage Disclosure of Proxy Voting Records by Mutual Funds. With the aim of improving investment returns by mutual funds and investment trusts, make necessary efforts so that the Investment Trust Association amends its rules on

proxy voting to require members to publicly disclose their actual proxy voting record.

- C. Facilitate Proxy Voting by Foreign Shareholders. With the aim of strengthening corporate governance, direct the Financial Supervisory Agency and the Ministry of Justice to examine necessary changes to the Commercial Code and to other rules on exercising proxies by subcustodians and global custodians that will facilitate the effective exercise of proxy votes by overseas beneficial owners.

## DISTRIBUTION

- I. **Airport Landing and User Fees.** The United States urges Japan to improve the business and tourism climate in Japan, and thereby help boost the economy, by:
  - A. Immediately reducing landing and user fees at Narita and Kansai International Airports, which would benefit both Japanese consumers and industry;
  - B. Ensuring that landing and user fees in Central Japan International Airport (Centrair) are competitive on a worldwide scale and negotiated in a transparent manner so as to avoid international charges subsidizing domestic charges;
  - C. Opening the formula used to calculate landing fees at Japan's international airports to public comment; and
  - D. Ensuring that the landing fee calculation is transparent both for domestic and international flights, and includes only those costs associated with the use of airport runways and facilities, as prescribed by IATA.
- II. **Airline Sales Distribution.** Japan is one of very few countries that enforce the IATA Minimus 70-percent low pricing band on tickets sold by airlines, preventing them from offering competitive discount fares. Ending this practice would stimulate travel by giving the public access to a wider array of fares with greater control of their travel choices and help reach Japan's goal of increasing inbound tourism. It would also create a competitive market for Internet and other published airline ticket sales. The United States urges Japan to end this practice and proposes that further discussion to this end be held in air services negotiations between the appropriate authorities.
- III. **30-Day Advance Fare Filing Requirement.** Current Ministry of Land, Infrastructure, and Transportation regulation stipulates that all airline ticket fare changes "must" be filed 30 days in advance. In reality, this regulation is not enforced and is out of date with Internet and computer filing systems. The global pace of business necessitates that Japan permit fare filings on much shorter notice, thus permitting airlines to price fares in a competitive market that changes daily. The current system raises costs to consumers and airlines. Furthermore, just as in the instance of IATA pricing, Japan is one of only a few nations that requires fare filings 30 days in advance. Therefore, the United States proposes that further discussion on this subject be held in air services negotiations between the appropriate authorities. The issue of changing the double approval regime to a double disapproval regime should also be discussed in the air services negotiations.
- IV. **Move from Cost of Insurance and Freight (CIF) to Free on Board (FOB) for Duty Calculation on Low-Value Items.** Japan's use of CIF to calculate duty on international shipments adds the cost of insurance and shipping to the value of goods being shipped, and artificially increases the number of shipments over the 10,000-yen *de minimis* line subject to duty. FOB is the fairest valuation method for determining duty on low-value items, and its use would ease the work of Customs and Tariff Bureau officials and reduce

costs in Japan. The United States urges Japan to adopt the FOB method for calculating duty on low-value goods at entry.

- V. ***De Minimis.*** The United States urges Japan to increase the Customs Law *de minimis* limit from 10,000 yen to 30,000 yen. This change will reduce the workload for both Customs and express carriers and streamline the customs clearance process.
- VI. **Further Reduce Charges in International Physical Distribution Special Zones.** The reduction of charges related to customs processing in International Physical Distribution Special Zones in April 2003 increased the competitiveness of Japan's international ports, and the United States applauds Japan's subsequent decision to reduce charges nationwide by 50 percent from April 2004. The United States urges Japan to continue its pro-growth actions by reducing these charges to zero.
- VII. **Nippon Automated Cargo Clearance System (NACCS).** The United States appreciates Japan's effort over the past year to have NACCS set more user-friendly fees and urges Japan to ensure that NACCS takes user comments into consideration in any future changes to its fee system.
- VIII. **Facilitation of Credit/Debit Card and ATM Services and Acceptance.** The use of credit, debit, and ATM cards is expanding at a rapid rate worldwide, and in the United States, Europe and Canada, 90 percent of all merchants accept credit or debit cards and over one-third of all purchases are made with these cards. Low card acceptance at both traditional merchants and ATMs in Japan inconveniences Japanese residents and is also a common complaint of foreign visitors to Japan. The United States notes that about 100 public hospitals are now accepting or preparing to accept credit and debit card payments, and in the context of the e-Japan II initiative and the spirit of Prime Minister Koizumi's goal of doubling Japan's inbound tourists from overseas by 2010, the United States urges Japan to:
- A. Further promote the use of credit and debit cards by businesses and as payment for government services;
  - B. Mandate compliance with international PIN security and network encryption standards across ATM networks in Japan; and
  - C. Strictly enforce laws and regulations relating to credit card fraud.