JAPAN

TRADE SUMMARY

The U.S. goods trade deficit with Japan was \$72.7 billion in 2008, a decrease of \$10.1 billion from \$82.8 billion in 2007. U.S. goods exports in 2008 were \$66.6 billion, up 6.2 percent from the previous year. Corresponding U.S. imports from Japan were \$139.2 billion, down 4.3 percent. Japan is currently the fourth largest export market for U.S. goods.

U.S. exports of private commercial services (*i.e.*, excluding military and government) to Japan were \$40.2 billion in 2007 (latest data available), and U.S. imports were \$24.5 billion. Sales of services in Japan by majority U.S.-owned affiliates were \$54.3 billion in 2006 (latest data available), while sales of services in the United States by majority Japan-owned firms were \$83.5 billion.

The stock of U.S. foreign direct investment (FDI) in Japan was \$101.6 billion in 2007 (latest data available), up from \$92.4 billion in 2006. U.S. FDI in Japan is concentrated largely in the finance/insurance, manufacturing, and nonbank holding companies sectors.

REGULATORY REFORM OVERVIEW

The United States-Japan Regulatory Reform and Competition Policy Initiative

Through the United States-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative), the U.S. Government has continued to urge Japan to address a number of regulatory and other business environment issues that have served to unnecessarily limit competition, stymie the introduction of innovative products and services, or otherwise hinder access for U.S. products and services in Japan's market. The U.S. Government put forward a comprehensive list of reform recommendations to Japan in October 2008 to begin engagement with Japan under the Initiative's eighth annual cycle of work. This list included comprehensive recommendations relating to specific industry sectors as well as those addressing cross-cutting business environment issues.

A summary of some of the key sectoral and structural regulatory reform recommendations made to Japan is presented in the following two sections.

SECTORAL REGULATORY REFORM

Telecommunications

In its 2008 Regulatory Reform Initiative recommendations, the U.S. Government continued to urge that Japan ensure fair market opportunities for emerging technologies and business models, develop a regulatory framework for converged and Internet-enabled services, and strengthen competitive safeguards on dominant carriers. The U.S. Government also continues to request that Japan improve transparency in rulemaking and ensure the impartiality of its regulatory decision making, including by abolishing the legal requirement that the government own one-third of the dominant carrier, Nippon Telegraph and Telephone (NTT).

Interconnection: Japanese laws and regulations do not prevent NTT's regional carriers from imposing high rates and onerous conditions on their competitors for interconnection. Japan's Ministry of Internal Affairs and Communications (MIC) made further revisions to its Rules for Interconnection Charges,

resulting in modest reductions in interconnection rates, which fell another 3.4 percent in April 2008, although these rates are still high by international standards. The U.S. Government has encouraged MIC to ensure that reasonable interconnection terms and conditions and competitive rates are established for such facilities, particularly as NTT continues deployment of its Internet Protocol (IP) based Next Generation Network replacing the analog network.

Dominant Carrier Regulation: NTT continues to dominate Japan's fixed line market through its control over almost all "last-mile" connections. As Japan's broadband users turn from digital subscriber line (DSL) (where competition, based on regulation, was vibrant) to optical fiber, NTT's competitors fear NTT will expand its dominant position through control of the fiber-to-the-home (FTTH) market and by bundling NTT fixed services with those of NTT DoCoMo, the dominant wireless operator. In October 2007, MIC issued a revised "New Competition Promotion Program 2010" in an effort to address competition concerns as suppliers increasingly offer telecommunications services over IP based networks. The U.S. Government has urged Japan to speed the plan's implementation and will continue to monitor MIC's implementation of the program.

Universal Service Program: Japan approved a system, beginning in January 2007, for NTT East and NTT West and their competitors to collect a universal service fee from voice services subscribers. MIC has undertaken periodic reviews to determine whether this amount should be adjusted to more accurately reflect costs, and has endorsed a proposal to increase significantly the universal service fees. NTT regional carriers (the only carriers able to benefit from the fund) then receive these fees through the universal service fund to offset the costs of providing services in rural areas. The U.S. Government has urged Japan to broaden the base of this fund's potential beneficiaries and ensure it is implemented in a competitively neutral manner. Current cross-subsidization of NTT West by NTT East using interconnection revenue (ostensibly to address NTT West's higher network costs resulting from the higher number of rural subscribers) appears redundant given the existence of the fund, and the U.S. Government has urged the abolition of this cross-subsidy.

Mobile Termination: Like most countries, Japan uses the "Calling Party Pays" system, imposing the entire cost of termination on the calling party (enabling mobile subscribers to benefit from free incoming calls). NTT DoCoMo, the dominant incumbent mobile carrier, announced March 2, 2009, that it would lower its termination rates by over 10 percent, continuing incremental rate reductions implemented over the past 10 years. Mobile interconnection rates, however, still remain high by international standards and also compared to fixed line rates in Japan. Despite recognizing DoCoMo as a dominant carrier in 2002, MIC does not require DoCoMo to publish its costs or explain how its rates are calculated. With new entrants now in the mobile sector, the U.S. Government will closely monitor actions both by DoCoMo and MIC to ensure the possibility of effective competition.

New Mobile Wireless Licenses: Starting in 2005, MIC began opening the market to new mobile providers beyond the three main incumbents by auctioning blocks of spectrum to a limited number of new wireless entrants. In December 2007, MIC awarded two additional licenses for wireless broadband services. However, the complexity of factors MIC chose in determining how to evaluate applications raises questions about whether it achieved its stated goal of awarding these licenses based on objective criteria. Given the scarcity of spectrum and high demand for new technologies, the U.S. Government has urged MIC to consider alternative means, including auctions, to assign commercial spectrum in a timely, transparent, objective, and nondiscriminatory manner that adheres to principles of technology neutrality. The U.S. Government has also stressed to Japan the importance of ensuring reasonable "roaming" rates for competitors and Mobile Virtual Network Operators (MVNOs), an issue where MIC is making noticeable progress through policies and dispute mediation, as evidenced by an increase in service offerings launched by new entrants in 2007.

Information Technologies (IT)

Health IT: Government policies that fail to encourage interoperability, technology neutrality, and international harmonization, in addition to insufficient reimbursement incentives, are inhibiting the expansion of Japan's health IT services sector, an important market for U.S. companies. The U.S. Government has been urging Japan to foster interoperability and technology neutrality, facilitate vendor participation in government-sponsored projects that develop health IT systems, and implement reimbursement systems that reward use of innovative IT.

IT-Related Financial Reform: It is unclear whether Japanese regulations permit non-bank payment services for online transactions. The lack of clear regulations in this area impedes the ability of U.S. non-bank payment services providers to offer their services in Japan. The U.S. Government urges Japan to modify or enact regulations to make clear that non-bank payment services are permitted to further the goal of creating a robust financial services sector in Japan.

Privacy: Separate and inconsistent privacy guidelines among Japanese ministries have created an unnecessarily burdensome regulatory environment for U.S. business with regard to the storage and general treatment of personally identifiable information in Japan. The U.S. Government continues to urge Japan to develop clear and consistent implementing guidelines for the privacy law across ministries, modified only when necessary to conform to the unique characteristics of individual business sectors.

IPR Protection: The U.S. Government continued to urge Japan to adopt a number of new measures to improve and strengthen IPR protection. These include: improving copyright protection and enforcement; improving the efficacy of the patent application process; and actively working with the United States to develop ways to promote greater protection of IPR worldwide, especially in Asia. (*See also "Intellectual Property Rights Protection" in this chapter.*)

Government IT Procurement: The lack of transparency, excessive reliance on sole-source contracting, and restrictions on intellectual property ownership among other factors hinder the participation of U.S. companies in Japan's government IT procurement. The U.S. Government therefore has urged Japan to: expand disclosure of procurement information; broaden participation in evaluation committees; make it easier for companies to own intellectual property they develop through government contracts; apply competitive bidding rules to independent administrative entities and government-sponsored firms; and ensure contracts are swiftly concluded after bidders are chosen and are not backdated.

IT and Electronic Commerce Policymaking: Insufficient transparency in Japan's policymaking process for IT and electronic commerce has constrained U.S. company access. The U.S. Government has urged Japan to improve its policymaking process by seeking and considering industry input at all stages of policymaking. This will foster development of standards that promote technology neutrality, facilitate private sector participation in government-appointed advisory groups, and provide companies with adequate time to offer public comments and adjust to rule changes.

Medical Devices and Pharmaceuticals

Japan is the largest foreign market for U.S. medical devices and pharmaceuticals. The U.S. Government continues to urge Japan to ensure that its policies foster the private sector's development of innovative products and improve patients' access to such products.

Japan's Ministry of Health, Labor and Welfare (MHLW), in its 2007-2008 "Vision" policy papers, called for eliminating delays in drug and device approvals and improving the overall environment for these

industries in Japan. The U.S. Government supports these goals and, through the Regulatory Reform Initiative, has continued to urge Japan to make further changes to help achieve them. Such changes include: (1) ensuring that planned increases in reviewers lead to significant improvements in product approval times; (2) improving incentives for research and development of advanced medical products; (3) fostering simultaneous global drug development; (4) reforming product review and clinical trial consultation systems; (5) improving vaccine reviews; and (6) streamlining *in vitro* diagnostic product (IVD) approvals.

In its April 1, 2008, biennial price revision, the Japanese government adopted new reimbursement policies. Those policies include broadening the repricing rule based on market expansion to cover a wider range of drugs, regardless of whether the drugs experienced increased market share. Japan also adopted policies that imposed a stricter application of the "Foreign Average Price" (FAP) rule for medical devices. The U.S. Government continues to urge Japan to refrain from implementing reimbursement policies that hinder the development and introduction of innovative medical devices and pharmaceuticals. Such policies not only discourage companies from efficiently introducing advanced medical products to the Japanese market, a particular concern due to Japan's aging population, but also serve as a disincentive to investment in research and development.

Transparency of drug and medical device reimbursement decision making processes, including on potential further systemic changes, also remains critical. The U.S. Government has been urging Japan to build further on recent improvements in this area to foster a more open, predictable market.

Blood Products: Japan's 2002 Blood Law established a principle of "self-sufficiency" and includes a Supply and Demand Plan for the government to manage the blood market. The U.S. Government has been urging Japan to not restrict imports of plasma protein products so as to increase patient access to life-saving blood plasma therapies, eliminate labeling that implies U.S. products are not as safe as Japanese products, and increase the efficiency of product reviews. The U.S. Government also urges Japan to develop a reimbursement system for blood products that accounts for the unique nature of plasma protein therapy characteristics.

Nutritional Supplements: Japan has taken steps to streamline import procedures and to open its \$10 billion nutritional supplements market, although many significant market access barriers remain. Unusually burdensome restrictions on health and nutrition claims are a major concern. Only those products approved as Foods for Specific Health Uses (FOSHU) or Foods with Nutrient Function Claims (FNFC) are allowed to have health or structure/function claims. Producers of most nutritional supplements, however, are unable to obtain FOSHU or FNFC approval due to FOSHU's costly and time consuming approval process and to the limited range of vitamins and minerals that qualify for FNFC. Other concerns include: long lead times for food additive applications; high levels of import duties for nutritional supplements at quarantine stations due to naturally occurring traces of substances such as benzoic acid and sorbic acid, which Japan classifies as food additives; and a lack of transparency in the development of health food safety regulations.

Cosmetics and Quasi-Drugs: Japan is the world's second largest market for cosmetics and "quasi-drugs" after the United States, yet regulatory barriers continue to limit consumer access to safe and innovative products. Unlike the U.S. over-the-counter drug monograph system, Japan requires premarket approval for certain products classified as quasi-drugs under the Pharmaceutical Affairs Law. The approval process includes requirements that are burdensome, lack transparency, and do not appear to enhance product safety, quality, or efficacy. In addition, many types of advertising claims for cosmetics and quasi-drugs are prohibited in addition to burdensome paperwork for importing products. The U.S. Government is urging Japan to address these and other issues under the Regulatory Reform Initiative.

Financial Services

The Japanese Government has stated repeatedly its goal of improving the international competitiveness of Japan's financial sector. In December 2007, the Financial Services Agency (FSA) unveiled its "Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets," and – following the Japanese Diet's 2006 approval of broad legislation under the Financial Instruments and Exchange Law (FIEL) – submitted amendments to the FIEL in March 2008. The 2006 FIEL amended 89 financial laws and consolidated the remainder of related laws with the goal of establishing one cohesive set of rules. Specifically, the FIEL sought to enhance investor protection and promote the movement of financial assets into securities markets through cross-sectoral rules for investment product sales, management, and disclosure. However, given the hundreds of pages of statutes comprising the FIEL and relatively recent implementation of the law which began September 30, 2007, the FIEL's overall effect is still not discernable. Market participants are looking to see whether FIEL implementing regulations, interpretation, and enforcement are consistent and predictable.

Japan has improved the transparency and predictability of the financial regulatory system, but further progress is needed. In particular, the FSA could expand the body of written interpretations of Japan's financial laws. While the FSA has enhanced supervision and disclosure, it must continue to move forward to establish transparency and consistency in regulation and supervision of financial institutions to bring them in line with international standards and best practices and to help realize the government's goal of improving Japan's global competitiveness as a financial services center.

No-Action Letters and Written Interpretations: The FSA has made some efforts to enhance the effectiveness of Japan's no-action letter system, including by soliciting input from U.S. and other foreign firms on how best to improve the system. Use of the system, however, has not materially increased. The U.S. Government continues to recommend that the FSA explore ways to expand use of the no-action letter system. The U.S. Government also has encouraged the FSA to expand the written interpretations it provides, including through greater use of its "interpretive letter" system and increasing the number of "reference cases" published on the FSA Internet site.

Agriculture

Japan maintains many tariff and nontariff barriers against trade in the agricultural sector. The U.S. Government's October 2008 submission to Japan under the Regulatory Reform Initiative includes several recommendations to enhance the efficiency of the trading environment for agricultural products and the transparency of trade-related rules and regulations. These include: implementing a Maximum Residue Limit (MRL) regime that ensures that any enforcement actions taken when a violation occurs are no more trade restrictive than necessary; ensuring that Japan's pesticide residue policies to enhance organic trade are in compliance with international standards; completing the review of widely used food additives that are recognized as safe by the Food and Agriculture Organization (FAO) and World Health Organization (WHO) Joint FAO/WHO Evaluation Committee on Food Additives; and following international standards for the treatment of post-harvest fungicides. (See also *Standards, Testing, Labeling, and Certification* in this chapter.)

Plant Quarantine Issues: Japan's plant quarantine system includes measures that are not always based on internationally recognized science or standards. Japan frequently turns to nationwide bans on imported products in response to narrowly focused quarantines imposed by exporting countries in their home markets. For example, when a disease or pest outbreak is reported in a contained area of the United States, Japan tends to ban imports of all associated U.S. plant products regardless of their region of origin. Such steps are unnecessarily trade restrictive as they are not risk based. Through the Regulatory Reform

Initiative, the U.S. Government continues to encourage Japan to use pest risk analysis that is based on international standards, and to provide a scientific basis for its responses, as well as articulate how adopted quarantine measures accurately reflect the level of phytosanitary protection Japan has determined to be appropriate.

Japan's Ministry of Agriculture, Forestry, and Fisheries (MAFF) prohibits the entry of various fresh plant products due to the presence of pests, even though some of these pests are also present in Japan. Japan has a pest forecast system that monitors certain domestic pests and alerts producers to potential increased pest damage. The Japanese government has contended this system constitutes official control under the International Plant Protection Convention (IPPC), the international standard setting body for plant protection. According to the Japanese government, it must impose a similar system for imported commodities. Japan has made progress to harmonize legislation and standards with international standards, but recognizes that more work is needed to harmonize practices on other pests that may adversely impact U.S. exporters.

STRUCTURAL REGULATORY REFORM

Antimonopoly Law and Competition Policy

Although Japan has taken significant positive steps in recent years to bolster its competition regime, cartel activity and bid rigging persist. Additional measures to combat anticompetitive behavior would improve the business environment and further attention is needed to ensuring enforcement procedures are fair and transparent.

Improving Antimonopoly Compliance and Deterrence: Japan's Antimonopoly Act (AMA) provides for both administrative and criminal sanctions against cartel violators. Administrative penalty ("surcharge") levels remain too low, however, and criminal prosecutions, which should have the strongest deterrent effect against anticompetitive behavior, have been few and penalties against convicted company officials have been weak. The U.S. Government continues to urge Japan to take steps to maximize the effectiveness of enforcement against hard-core violations of the AMA, including by augmenting administrative and criminal penalties, extending the statute of limitations, and strengthening the effectiveness of the Japan Fair Trade Commission's (JFTC) leniency program (which eliminates or reduces penalties for whistle blowing companies). The JFTC's ability to enforce the AMA effectively is also hindered by a lack of employees with post-graduate economics training, a factor that undermines JFTC ability to engage in the careful economic analysis necessary to properly evaluate non-cartel behavior. The U.S. Government continues to urge the JFTC to improve its economic analysis capabilities.

Improving Fairness and Transparency of JFTC Procedures: Japan introduced a system in January 2006 that empowered the JFTC to make determinations of AMA violations without a formal administrative hearing, with respondents being afforded the right to seek administrative review of the decision only after the decision was put into place. Although the JFTC allows companies subject to a proposed cease-and-desist or surcharge payment order to review the evidence relied upon by JFTC staff and to submit evidence and make arguments in their defense prior to an order being issued, questions have been raised as to whether this system provides sufficient due process protections. To ensure further credibility and transparency of JFTC hearing procedures, the U.S. Government has asked Japan to review the *ex post* hearing system and take necessary measures to ensure that respondents are afforded procedural fairness in the JFTC decision making and appeals process, as well as to ensure that JFTC investigatory processes are conducted in accordance with generally accepted notions of fundamental procedural fairness.

Broadening Measures to Combat Bid Rigging: Japanese officials have implemented a series of measures to address the problem of frequent and persistent bid rigging. Apart from several cases in which the JFTC invoked the 2003 law against bureaucrat-led bid rigging (so-called kansei dango), the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has strengthened administrative sanctions against companies found by JFTC to have engaged in unlawful bid rigging. MLIT and nine other central government entities have also introduced an administrative leniency program to complement the JFTC leniency program (designed to help encourage individuals and companies to report anticompetitive acts), and Japan has put in place a series of measures aimed at ensuring a competitive bidding process for project contracts tendered at the central and local government levels. In June 2007, the Japanese Diet passed legislation aimed at controlling post-retirement employment by Japanese government officials in companies they previously helped regulate or were otherwise involved with while in government service, the so-called "descent from Heaven" (amakudari), which has been a factor in many bid rigging conspiracies. The U.S. Government has recommended that Japan strengthen measures to: prevent conflicts of interest in government procurement; improve efforts to eliminate involvement in bid rigging by government officials; expand administrative leniency programs; and further improve procurement practices to ensure open and competitive bidding.

Transparency

Transparency issues remain a top concern of U.S. companies operating in Japan's market. Through the Regulatory Reform Initiative, the U.S. Government has strongly urged Japan to adopt new measures to achieve a higher degree of transparency in governmental regulatory and policy making processes.

Advisory Groups: Although advisory councils and other government-commissioned study groups are accorded a significant role in the development of regulations and policies in Japan, the process of forming these groups can be opaque and nonmembers are too often not uniformly offered meaningful opportunities to provide input into these groups' deliberations. The U.S. Government continues to urge Japan to ensure transparency of advisory councils and other groups convened by the government by adopting new requirements to ensure ample and meaningful opportunities are provided for all interested parties, as appropriate, to participate in and directly provide input to these councils and groups.

Public Comment Procedures (PCP): Many U.S. companies remain concerned by inadequate implementation of the PCP by Japanese ministries and agencies. Examples include cases where comment periods appear unnecessarily short, as well as cases suggesting comments are not adequately considered given the brief time between the end of the comment period and the issuance of a final rule or policy. The U.S. Government has stressed the need for Japan to ensure its existing PCP is being fully implemented and to make additional revisions to further improve the system.

Transparency in Regulation and Regulatory Enforcement: To ensure the private sector has sufficient information about regulations and official interpretations of those regulations that are necessary to comply, the U.S. Government is urging Japan to specifically require its ministries and agencies to make public their regulations and any statements of policy of generally applicable interpretation of those regulations.

Privatization

The Japanese government's program to privatize the Japan Post Group, which has multi-billion dollar banking and insurance businesses in addition to its mail and parcel delivery operations, has passed several important milestones in the first year of the privatization process. The U.S. Government recognizes that reform in this area, if implemented in a fully market-oriented manner, can have an important positive

effect on the Japanese economy by stimulating competition and leading to a more productive use of resources.

The U.S. Government continues to carefully monitor the implementation of the Japanese government's postal reform efforts and to call on the Japanese government to ensure that all necessary measures are taken to achieve a level playing field between the Japan Post companies and private sector participants in Japan's banking, insurance, and express delivery markets.

In the area of express carrier services, the U.S. Government remains concerned by unequal conditions of competition between Japan Post Service and U.S. international express delivery providers. The U.S. Government urges Japan to enhance fair competition, including by ensuring Japan Post Service is subject to similar customs clearance procedures and costs for competitive services such as international express delivery services, and that subsidization of Japan Post Service's international express service by revenue from noncompetitive postal services is also prevented.

The U.S. Government also continues to emphasize the importance of transparency and disclosure for the successful implementation of the postal reform process. The U.S. Government has continued to urge the Japanese government to ensure that the process by which postal reforms proceed is made fully transparent, including by full and meaningful use of public comment procedures and through opportunities for interested parties to express views to related officials and advisory bodies before decisions are made. Timely and accurate disclosure of financial statements and related notes serves a key function in the privatization process, as does the continued public release of meeting agendas, meeting minutes, and other documents relevant to the process. The U.S. Government also looks to Japan to ensure that its triennial review of postal privatization is transparent and fully addresses the issue of equivalence of competition in the banking, insurance, and express delivery sectors. (*For discussion of Japan Post privatization and the postal insurance corporation, see "Insurance" under the Services Barriers section.*)

Commercial Law

Japan undertook a major reform of its commercial law by enacting a new Corporate Code, which entered into force May 1, 2006. Among other provisions, the code now permits the use of certain modern merger techniques, including domestic and cross-border triangular mergers. These new provisions, however, have not yet been as effective as had been hoped in facilitating foreign investment into Japan. This may reflect the limited range of tax-advantaged merger tools and corporate governance systems that do not adequately reflect the interests of shareholders.

Through the Regulatory Reform Initiative, the U.S. Government continues to urge Japan to improve further its commercial law and corporate governance systems to promote efficient business practices and management accountability to shareholders in accordance with international best practices. Specifically, the U.S. Government is urging Japan to identify and eliminate impediments to cross-border mergers and acquisition, including the availability of reasonable qualifying rules for tax-deferred treatment for many such transactions, and to take measures to ensure that shareholder interests are adequately protected when Japanese companies adopt anti-takeover measures or engage in cross-shareholding arrangements.

The U.S. Government also continues to encourage Japan to identify legislation and other measures necessary to strengthen corporate governance mechanisms, including by: facilitating and encouraging active proxy voting by institutional investors such as pension and mutual funds; tightening the definition of outside directors; allowing the boards of directors of Japanese corporations to delegate certain decision making functions to committees composed solely of independent directors; and encouraging the stock exchanges to adopt listing rules and guidelines that will improve the corporate governance of listed

companies and ensure that the interests of minority shareholders are protected when the board of directors decides to issues new shares, conduct a reverse stock split or allocate shares to third parties. The U.S. Government also continues to request that Japan amend Article 821 of the Company Law to prevent adverse effects on U.S. companies seeking to legitimately conduct their primary business in Japan through Japanese branch offices.

Legal System Reform

Japan imposes restrictions on the ability of foreign lawyers to provide international legal services in Japan in an efficient manner. The U.S. Government continues to urge Japan to further liberalize the legal services market by allowing foreign lawyers to form professional corporations and establish multiple branch offices in Japan whether or not they have established a professional corporation, counting all of the time foreign lawyers spend practicing law in Japan toward the three year experience requirement for licensure as a foreign legal consultant, and speeding up the registration process for new foreign legal consultants. The U.S. Government has also requested that Japan take measures to ensure that no legal or Bar Association impediments exist to Japanese lawyers becoming members of international legal partnerships with lawyers outside Japan without restriction, and to ensure that foreign legal consultants can legally provide alternative dispute resolution (ADR) services and represent parties in any international ADR proceedings taking place in Japan.

In order to encourage victims of trade secret theft to cooperate with prosecutors in bringing criminal charges against the wrongdoers, the U.S. Government is urging Japan to adopt necessary procedures that will ensure that the content of a trade secret will not be disclosed to the public in the criminal trial.

Distribution and Customs Clearance

The U.S. Government welcomes Japan's work to formulate an Authorized Economic Operator (AEO) system, which allows exporters with good compliance records to process goods more expeditiously through Customs. Japan Customs, however, currently does not allow post-export declarations, and requires brokers to declare express items at specific Customs offices, which limits flexibility and potentially increases processing costs. To further facilitate trade, the U.S. Government is urging Japan under the Regulatory Reform Initiative to allow customs brokers to make post-export declarations for items valued at less than 250,000 yen (about \$2,500), and allow those brokers using the Japan Customs' Nippon Automated Cargo Clearance System (NACCS) automated database to declare express items at any Customs office. To facilitate more efficient cargo flows, the U.S. Government is recommending that Japan exempt AEO exporters from paying the 5 percent consumption tax for cleared cargo. Currently, Japan Customs refunds this tax, but an exemption would reduce the administrative burden of filing for a refund. The U.S. Government also is recommending that Japan raise the Customs Law *de minimis* ceiling from 10,000 yen (about \$100) to at least 20,000 yen or higher, in line with international best practice to reduce workloads and maximize efficiency.

IMPORT POLICIES

Rice Import System: Japan's highly regulated and non-transparent importation and distribution system for imported rice limits meaningful access to Japanese consumers. In 1999, Japan established a tariff-rate quota (TRQ) of approximately 682,000 metric tons (milled basis) for imported rice. The Staple Food Department (SFD) of MAFF manages imports of rice within the TRQ through periodic ordinary minimum access (OMA) tenders and through the simultaneous buy-sell (SBS) tenders. Imports of U.S. rice under the OMA tenders are destined almost exclusively for government stocks. MAFF releases these stocks exclusively for non-table rice users in the industrial food processing or feed sector and for re-

export as food aid. In calendar year 2007, U.S. rice exports to Japan were valued at \$206 million, representing approximately 322,000 metric tons. Only a small fraction of this rice reaches Japanese consumers identified as U.S. rice, despite industry research showing Japanese consumers would buy U.S. high-quality rice if it were more readily available.

Until 2008, Japan generally met its WTO import volume commitments. However, Japan failed to import the full in-quota TRQ quantity for rice in Japan fiscal year 2007, which started on April 1, 2007, and ended on March 31, 2008. The unusual conditions in 2007/2008 that resulted in global rice prices that were higher than normal, although still below Japan's domestic prices, exposed several weaknesses in Japan's administration of its TRQ system for rice. The U.S. Government's expectation is that Japan will completely fill its in-quota TRQ quantity for Japan fiscal year 2008, and we continue to closely monitor Japan's rice import tendering process.

The Japanese government's Maximum Residue Limits policy has resulted in excessive testing requirements for rice imports which also hamper trade in U.S. rice with Japan. Rice and wheat, however, are the only commodities for which Japan requires multiple tests, including a separate test by the rice industry. This testing has resulted in a disproportionate increase in the cost of bringing U.S. rice to market, particularly for rice purchased under their SBS system because of smaller import lot sizes.

Wheat Import System: Japan requires wheat to be imported through MAFF's Food Department, which then resells the wheat to Japanese flour millers at prices substantially above import prices. These high prices discourage wheat consumption by increasing the cost of wheat-based foods in Japan. In 2007, MAFF revised the wheat import regime to allow more frequent adjustment to the resale price and therefore more closely reflect international price movements. Coupled with higher global wheat prices, the resale price to flour millers has increased 55 percent. The U.S. Government remains concerned by Japan's operation of a state trading entity for wheat and its potential to distort trade.

Pork Import Regime: Japan is the largest export market for U.S. pork on both a volume and a value basis (importing 425,000 metric tons in 2008, worth \$1.5 billion). The import tariff for pork is established by a gate price system that applies a 4.3 percent *ad valorem* tariff when the import value is equal to or higher than the administratively established reference price. Imports that fall below the reference price pay an additional duty equal to the difference between the import value and the reference price.

Beef Safeguard: Japan negotiated a beef safeguard during the Uruguay Round to protect domestic producers in the event of an import surge. The safeguard is triggered when the import volume increases by more than 17 percent from the level of the previous Japanese fiscal year on a cumulative quarterly basis. Once triggered, the safeguard remains in place for the rest of the fiscal year. If triggered, beef tariffs will rise to 50 percent from 38.5 percent.

Fish Products: Japan was the most important export market for U.S. fish and seafood products for over 30 years, although the European Union (EU) surpassed Japan in 2007 when 20 percent of U.S. seafood exports went to Japan and 24 percent went to the EU. That trend continued in 2008, when U.S. exports to Japan again accounted for 20 percent of U.S. seafood exports. An overall decrease in Japanese seafood consumption and therefore imports, as well as the growing seafood demand in the United States, the EU, and other countries, appear to be important reasons for this shift.

Japan's tariffs on seafood imports are generally low, although tariffs on certain products remain an impediment to U.S. exports, making the products too expensive for Japanese importers in an increasingly competitive global marketplace. Market access is also not seamless for some products. For example, Japan maintains several species and product-specific import quotas on pollock, Pacific cod, Pacific

whiting, mackerel, sardines, and squid. Import quotas also exist for specific products such as pollock and cod roe, and surimi. Administration of the system has improved considerably over the years and it is expected that obstacles to Japanese importers and processors will continue to be reduced as the need for protection provided by the quotas continues to decline. While Japan cut tariffs as a result of the Uruguay Round, it did not change its import quotas. As part of ongoing WTO Doha negotiations, Members including the United States and Japan have committed to clarify and improve rules on fisheries subsidies.

High Tariffs on Beef, Citrus, Dairy, and Processed Food Products: Japan maintains high tariffs on a number of food products that are important exports for the United States, including red meat, citrus, wine, and a variety of processed foods. Examples of double digit import tariffs include 38.5 percent on beef, 32 percent on oranges, 40 percent on processed cheese, 29.8 percent on natural cheese, 17 percent on apples, 20.4 percent on cookies, up to 17 percent on table grapes depending on the season of the year, and 15 percent to 29.8 percent on wine depending on the Harmonized Tariff System (HTS) classification. These high tariffs generally apply to food products where Japan has domestic production. Tariff reductions are a high priority for the U.S. Government in the Doha Development Agenda agriculture negotiations.

Wood Products and Building Materials: Japan continues to restrict imports of certain manufactured wood products through tariff escalation (*i.e.*, progressively higher tariffs based on the level of processing of the wood product). The elimination of tariffs on wood products remains a long standing U.S. Government objective.

Leather/Footwear: Japan continues to apply a TRQ on leather footwear that substantially limits imports into Japan's market, and establishes these quotas in a nontransparent manner. The U.S. Government continues to seek elimination of these quotas.

STANDARDS, TESTING, LABELING, AND CERTIFICATION

Japan's enforcement of national standards hinders trade in certain farm, forest, and industrial products. U.S. industry has raised concerns that Japan's stringent testing methods and low tolerances for regulated substances such as pesticides and food additives make it difficult to satisfy import requirements for many products. The U.S. Government is urging Japan to use science-based standards and implement risk-based enforcement policies as the least trade restrictive measures that also satisfy consumer safety concerns.

Sanitary and Phytosanitary Measures

Beef: On July 27, 2006, Japan partially reopened its market to U.S. beef and beef products. Except for approximately one month from December 2005 to January 2006, Japan's market had been effectively closed to U.S. beef since the December 2003 detection of a cow with Bovine Spongiform Encephalopathy (BSE) in Washington State.

Japan allows imports of U.S. beef and beef products from animals aged 20 months or younger. However, the protocol which implemented this limited reopening has prevented the United States from regaining all but a small portion of its historic level of exports to the Japanese market. Before the ban, Japan was the largest export market for U.S. beef and beef products, totaling roughly \$1.4 billion annually.

The U.S. Government has repeatedly urged Japan to bring its BSE measures in line with international guidelines set by the World Organization for Animal Health (OIE) by allowing imports of all U.S. beef and beef products derived from animals of all ages deemed safe under OIE guidelines. In May 2007, the OIE determined that the United States is a "controlled risk" country for BSE, a determination based on internationally accepted science. The U.S. Government remains highly concerned

by Japan's unwillingness to adopt science-based, international guidelines for BSE under which beef and beef products can be safely traded. The U.S. Government will continue to work vigorously to normalize trade to this important market.

Enforcement of Maximum Residue Limits (MRLs): With Japan's adoption of an MRL positive list system in May 2006, it became apparent that Japan's Ministry of Health, Labor and Welfare's (MHLW) MRL enforcement policy increases the risk to suppliers of being penalized for MRL violations incurred by other exporters. After a single MRL violation, MHLW increases testing to 30 percent of that agricultural commodity originating from that country. In the event that a second violation occurs within a 12 month period of the first violation for the same commodity and country, MHLW imposes a 100 percent test-and-hold policy against the agricultural commodity from the entire exporting country.

As a result of ongoing consultations and MHLW's positive assessment of the effectiveness of the U.S. system, MHLW implemented a new MRL enforcement program in August 2007 that exclusively penalizes the exporter in violation of Japan's tolerance, but only in cases where the U.S. tolerance for the particular commodity and pesticide is equal to or more restrictive than Japan's tolerance. However, when the exporting country's MRL is less restrictive than Japan's, this policy provides no assurances that U.S. agricultural exports will not be subject to country-wide sanctions. The U.S. Government continues to press Japan to adopt MRL enforcement measures that conform to international standards.

Food Additive Classification for Post-Harvest Fungicides: Japan's classification of post-harvest fungicides as food additives contradicts international standards. Countries assessing the risk associated with a particular pesticide generally perform one risk assessment for pre- and post-harvest application. Under the Japanese system, a risk assessment for pre-harvest application and an additional pest risk assessment for the same fungicide for post-harvest treatment are required. This is due to Japan's unusual policy of classifying post-harvest fungicides as food additives. The costly and lengthy review process associated with Japan's policy deters companies from seeking MRLs for its products and precludes U.S. producers from using safer and more effective pesticides on products destined for Japan. The U.S. Government continues to raise this issue in high-level trade policy fora to encourage Japan to conform to international practices by eliminating its policy of classifying post-harvest fungicides to food additive risk assessments.

Microbial Content Standards: Japan's standards under the Food Sanitation Law for microbial content on frozen foods are, in certain instances, impractical and overly restrictive, particularly for foods that require cooking before consumption.

Fumigation Standards: Japan requires a separate fumigation trial and evaluation for each new horticultural variety before its entry into Japan's market. Separate fumigation trails for new varieties are not based on science, and therefore these practices should be eliminated.

Poultry: Since 2002, Japan has imposed several national and statewide bans on the import of U.S. poultry, poultry meat, and eggs due to the detection of exposure to avian influenza (AI) in U.S. domestic birds, both high pathogenic avian influenza (HPAI) and low pathogenic avian influenza (LPAI). The OIE guidelines as well as the WTO Sanitary and Phytosanitary agreement provide for importing countries to impose bans on imports of only certain commodities from affected regions (zones) of the exporting country. Japan bans almost all poultry commodities from the entire country in the event of HPAI, and the entire state in the event of LPAI. Japan's actions have not been consistent with international standards and have disrupted trade in poultry and related products.

Standards

Restrictive Food Additive List: Japan's regulation of food additives has a restrictive effect on imports of several U.S. food products, especially processed foods. Many additives that are in wide use in the United States and throughout the world are not allowed in Japan, including many newer additives that are considered safer than older alternatives. In addition, many of Japan's approved additives have conditions further limiting the use of these specific food additives on a product-by-product basis.

U.S. manufacturers have complained about the prolonged approval process for indirect food additives (*i.e.*, additives that do not remain on food, such as solvents). In 2002, Japan created a list of 46 food additives for expedited review; a number of additives still have not been reviewed and approved, notwithstanding the availability of extensive safety data. The U.S. Government has urged Japan through the United States-Japan Regulatory Reform Initiative to complete review of the 46 food additives and expedite the review process for food additives in general.

Organics: U.S. organic exports to Japan continue to be limited by Japan's ban on alkali extracted humic acid, a production substance that is allowed for use on U.S. organic crops. In addition, Japan's zero tolerance policy for pesticide residues on organic products is not consistent with international standards, and in practice appears to be more thoroughly enforced for imported organic products.

Marine Craft: Japan continues to maintain an inspection regime for new boats and marine engines that is unique in the world in its complexity. Japan's regulations, written and administered by the Ministry of Land, Infrastructure and Transport and the Japan Craft Inspection Organization, can be complicated and vague. The U.S. Government has been engaged with the Japanese government to urge improvements and raise awareness. Japan's adoption of 40 ISO standards as its relevant regulations has been a positive step. The U.S. Government encourages Japan to continue this trend as well as to use or accept third-party documentation and certification of U.S boats to these Japanese ISO-based standards and non-ISO-based standards.

Building Size, Designs, and Wood Products

Japan has adopted and implemented regulations with respect to indoor air quality and chemical emissions, and may be considering additional steps. The U.S. Government will continue to monitor regulatory developments in this area and urge that Japan ensures transparency in any resulting rule making process. In addition, Japan's fire testing standards for wood frame assemblies is ambiguous and open to interpretation by testing facilities, lack of a uniform understanding of requirements makes it more difficult for wood products to meet Japan's fire testing requirements.

Biotechnology

Japan is the world's largest importer of bioengineered grains and annually imports about 15 million metric tons of U.S. corn and 3.3 million metric tons of U.S. soybeans, mostly for use as feed or for processing. In 2007, U.S. exports to Japan of these commodities alone were worth \$3.7 billion. To both secure bilateral trade in grains and increase global food security, the United States and Japan share a common interest in promoting effective biotechnology approval and regulatory policies.

Japan's Food Safety Commission conducts risk assessments in support of product evaluations by the Ministry of Health, Labor and Welfare and the Ministry of Agriculture, Forestry and Fisheries. Japan's regulatory system is complex and compliance is costly, which makes it difficult for products developed by Japanese researchers to be commercialized, and there is a concern that the continued growth in the

number and complexity of new biotechnology applications in coming years could strain the regulatory system. There is also the real possibility of trade disruptions from an unapproved bioengineered variety showing up in trace amounts in imported grain or processed foods. To avoid disrupting trade, the U.S. Government is actively engaging with Japan's regulatory agencies to encourage a risk based, case-by-case approach when dealing with unapproved varieties.

Although Japan is the largest *per capita* importer of bioengineered crops, no consumer-ready foods with recognizable bioengineered ingredients are sold in Japan. One factor that keeps bioengineered foods out of the supermarket is Japan's labeling requirement. As of yet, no Japanese food manufacturer or retailer has been willing to test the market for a consumer-ready food that is labeled with ingredients derived from modern biotechnology.

There is no commercial production of biotechnology crops in Japan, generally due to concerns from surrounding farmers about cross pollination and concerns from agricultural cooperatives opposing biotechnology crops. In addition to Japan's national regulatory system, 12 prefectural and local governments maintain rules, generally not based on science, which further limit cultivation of bioengineered crops. These rules, combined with local regulations and public pressure on research institutions, have made it increasingly difficult for technology companies to secure sites for field trials, mandated under the central government's approval process.

The U.S. Government will continue to encourage Japan to address these issues and continue to participate in discussions on biotechnology policy advancement and regulation in international fora (*i.e.*, the WTO, the Codex Alimentarius Commission, the OECD, and the APEC forum) and through international agreements dealing with international movement of bioengineered crops.

Labeling

Proprietary Ingredient Information Disclosure Requirement for Import: As part of its product classification process for new-to-market food and dietary supplement products, Japan mandates that all ingredients and food additives be listed by name, along with content percentages, and include a description of the manufacturing process. In addition to being overly burdensome, this process runs the risk that proprietary information may be obtained by competitors.

Labeling of Beef: In 2007, the Ministry of Agriculture, Forestry, and Fisheries adopted voluntary labeling guidelines that bar the use of the term "wagyu" on cattle not born and raised in Japan. The U.S. Government is concerned by this step and is monitoring the implementation of this measure.

GOVERNMENT PROCUREMENT

Japan is a Signatory to the WTO Agreement on Government Procurement (GPA). For procurement of construction services by sub-central and government enterprises covered under the GPA, Japan applies a threshold of approximately \$22 million, which is three times the threshold applied by the United States.

Construction, Architecture, and Engineering

U.S. companies annually obtain far less than 1 percent of projects awarded in Japan's massive public works market, valued at \$163 billion in 2008. Two bilateral public works agreements are in effect: the 1988 United States-Japan Major Projects Arrangements (MPA) (updated in 1991); and the 1994 United States-Japan Public Works Agreement, which includes the Action Plan on Reform of the Bidding and Contracting Procedures for Public Works (Action Plan). The MPA included a list of 42 projects in which

international participation is encouraged. Under the Action Plan, Japan must use open and competitive procedures for procurements valued at or above the thresholds established in the GPA. The United States raises public works issues in the annual Expert-Level Meetings on Public Works under the United States-Japan Trade Forum.

Problematic practices continue to limit the participation of U.S. design/consulting and construction firms in Japan's public works sector, including bid rigging (*dango*), under which companies consult and prearrange a bid winner. The U.S. Government continues to stress the need for Japan to take more effective action to address this pervasive problem. The U.S. Government also asked Japan to take measures to address excessive low-bidding and recognizes that Japan is attempting to do so through the increased use of Overall Greatest Value Method procurements and other measures.

The U.S. Government has raised its concerns with Japan's use of excessively narrow Japan-specific qualification and evaluation criteria that preclude U.S. firms from competing for projects. The U.S. Government has also asked Japan to: (1) develop procedures to simplify the qualification process for foreign firms that have relevant experience outside of Japan, as well as to ensure that all project-related qualification requirements are made public, as required by the GPA and the bilateral agreements; (2) address problems related to the treatment of joint venture members, extremely low design fees, lack of clarity in design fee structures, and excessive and costly documentation requirements for design bids; and (3) rectify the excessive use of the GPA operational safety exemption for railroad procurements.

The U.S. Government is paying special attention to several major projects covered by the public works agreements that are of particular interest to U.S. companies; these projects should provide important opportunities for U.S. firms. These projects include: the Haneda Airport development and expansion; the second phase of Kansai International Airport; the Central Japan International Airport; the Kyushu University Relocation Project; major expressway projects, including the Gaikan Expressway Project and Metropolitan Expressway Shinagawa Route Project; Japan Post Projects; major public buildings, railroad procurements, urban development and redevelopment projects; major Private Finance Initiative (PFI) projects; and the MPA projects still to be undertaken or completed.

INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

The U.S. Government continues to pursue its IPR protection agenda with Japan through bilateral consultations and cooperation, as well as in multilateral and regional fora. For its part, Japan continues to make progress in improving the protection of IPR. The U.S. Government, however, has identified several areas in Japan's IPR protection regime where further action by Japan is needed.

Patents

The U.S. Government continues to urge Japan to adopt a 12-month patent application filing grace period, similar to that provided under U.S. law, to harmonize the two systems and enhance U.S. innovators' protection against a possible loss of patent rights in Japan. The U.S. Government also continues to urge Japan to implement procedures to avoid a piecemeal approach to patent examinations that results in unnecessarily lengthy delays in granting patents.

Copyrights

Adequate protection of intellectual property is critical for the continued development and competitiveness of content-related industries, and is a vital component to advancing electronic commerce and a well-functioning digital economy. The U.S. Government encourages Japan to consider ways of improving its

Internet service provider liability law to ensure it provides adequate protection for the works of rights holders on the Internet or the appropriate and necessary balance of interests among telecommunications carriers, service providers, rights holders, and website owners. The U.S. Government continues to monitor Japan's efforts to promote digital content distribution and urges that Japan work to preserve and support the international framework governing the exclusive rights of authorship and the incentives to create in order to keep pace with distribution-related technologies.

The U.S. Government is urging Japan to continue efforts to reduce piracy rates, including methods to protect against piracy on the Internet and other digital environments. Police and prosecutors should be given *ex officio* authority to enable them to prosecute IPR crimes on their own initiative, without the requirement of rights holder consent. To develop Japan's digital communication networks, Japan's Copyright Law should better protect the technological adjuncts to copyright protection such as strengthening the remedies for trafficking in the tools used to circumvent copy and access controls.

The U.S. Government is also encouraging Japan to consider clarifying the scope of the personal use exception, both as it applies to the Internet and to book piracy in the educational context.

The U.S. Government also continues to strongly urge Japan to extend the term of protection for all the subject matter of copyright and related rights to life plus 70 years, or where the term of protection of a work (including a photographic work), performance, or phonogram is calculated on a basis other than the life of a natural person, to 95 years.

The Japanese government is coordinating an ongoing discussion among stakeholders of these and other related issues and may revise Japanese laws in the near term. The U.S. Government welcomes this process and encourages Japan to ensure it is open, inclusive, and transparent, and offers all stakeholders fair opportunities to express views.

Border Enforcement

Border enforcement is a critical component of effective IPR protection. The U.S. Government notes steps taken by Japan to strengthen its own border enforcement as well as to provide assistance to improve the border enforcement of key trading partners. The U.S. Government also welcomes revisions to the Customs Tariff Law, which went into force in 2007, including an expanded list of prohibited goods for export to include items that infringe copyrights and related rights, and strengthened penalty clauses for customs offences. It is important for the Japanese government to continue its aggressive interdiction of infringing articles and to vigorously apply new provisions of the Customs Tariff Law. Japan has positively contributed to the enhancement of IPR enforcement in fora such as the G-8, APEC, and the WTO TRIPS Council, and through border enforcement capacity building work in the Asia-Pacific region.

SERVICES BARRIERS

Insurance

Japan's private insurance market is the second-largest in the world, after that of the United States, with direct net premiums of an estimated 35.8 trillion yen (over \$300 billion) in Japan fiscal year (FY) 2007. In addition to the offerings of Japanese and foreign private insurers, substantial amounts of insurance are also provided to Japanese consumers by a web of insurance cooperatives (*kyosai*), and the Japan Post Insurance Co., Ltd. (a wholly government-owned entity of the Japan Post Group). Given the size and importance of Japan's private insurance market as well as the scope of the obstacles that remain, the U.S.

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Government continues to place a high priority on ensuring that the Japanese government's regulatory framework fosters an open and competitive insurance market.

Postal Insurance: Japan's postal life insurance system remains a dominant force in Japan's insurance market. At the end of Japan FY2007, there were approximately 62 million postal life and postal annuity insurance policies in force, with approximately 651,000 having been issued by the new Japan Post Insurance Co., Ltd., after it began operations on October 1, 2007, and the remainder held as assets of the Public Successor Corporation. In comparison, 127 million life and annuity policies were in force with all other life insurance companies combined. The U.S. Government has long-standing concerns about the postal insurance company's impact on competition in Japan's insurance market and is continuing to closely monitor the implementation of reforms. This includes the expectation that the principle of establishing equivalent conditions of competition between the Japan Post companies and the private sector, as outlined in Japan's basic postal reform law, will be fully achieved. A level playing field between the postal insurance company and private sector insurers is critical to cultivate competition, enhance consumer choices, encourage more efficient resource allocation, and stimulate economic growth.

The U.S. Government continues to urge Japan to take a number of steps to ensure equivalent treatment, including but not limited to: (1) ensuring equal supervisory treatment between Japan Post's financial institutions, including Japan Post Insurance, and private sector companies; (2) implementing adequate measures to prevent cross-subsidization among the newly created Japan Post businesses and related entities, including by ensuring the Japan Post companies' strict compliance with the Insurance Business Law's arm's length rule and requiring adequate financial disclosures to demonstrate that cross-subsidization is in fact not occurring; and (3) ensuring the company established to manage Japan's post office network will transparently and without discrimination select financial products, including insurance products, of private providers for distribution throughout the network.

The U.S. Government continues to call on Japan to ensure a level playing field between the postal insurance company and private insurers before the introduction of new or altered insurance products by the postal insurance company. Approval of new products by the new postal insurance company has shifted to a process whereby decisions are made by the Prime Minister (with the Commissioner of the Financial Services Agency acting as proxy) and Minister of Internal Affairs and Communications, after hearing the opinion of an appointed government advisory body. This process should be transparent and open to all parties. It is also critical that the process include careful analysis of, and full consideration given to, actual competitive conditions in the market and that private sector views are actively solicited and considered before decisions are made.

As modifications to the postal financial institutions and network subsidiary could have serious ramifications to competition in Japan's financial market, adequate transparency in implementation of the reforms passed by the Diet is essential. The U.S. Government has urged Japan to continue to take a variety of steps to ensure transparency, including providing meaningful opportunities for interested parties to exchange views with related government officials as well as members of government-commissioned advisory committees and groups before decisions, including those on new products, are made; and fully utilizing public comment procedures with respect to drafting and implementing regulations, guidelines, Cabinet Orders, and other measures. Timely and accurate disclosure provides important information as well as independent means to track and validate the privatization process.

Kyosai: Insurance businesses run by cooperatives, or *kyosai*, hold a substantial market share of insurance business in Japan. Some *kyosai* are regulated by their respective agencies of jurisdiction (the Ministry of Agriculture, Forestry and Fisheries, or the Ministry of Health, Labor and Welfare, for example) instead of by the Financial Services Agency (FSA), which regulates all other private sector insurance companies.

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These separate regulatory schemes undermine the ability of the Japanese government to provide companies and policyholders a sound, transparent regulatory environment, and afford *kyosai* critical business, regulatory, and tax advantages over their private sector competitors. The U.S. Government believes *kyosai* must be subject to the same regulatory standards and oversight as their private sector counterparts to ensure a level playing field and to protect consumers.

The Japanese government has taken some important steps since 2006 to bring more oversight to unregulated *kyosai*. Under these regulatory reforms, previously unregulated *kyosai* were required to apply to the FSA for new legal status by April 2008. Some of the cooperatives, which elected to become full-fledged insurance companies, have been held to the same regulatory standards as private sector insurers. Others opted to become "Small Amount Short Term Insurance Providers," which limits their product range and size and holds the firms to different requirements than those applied to private sector insurance companies. The remaining unregulated *kyosai* are required to close their businesses in 2009. With respect to *kyosai* regulated by ministries and agencies other than the FSA, the U.S. Government remains concerned by their continued expansion in Japan's insurance market and continues to call on Japan to bring these *kyosai* under FSA supervision.

Policyholder Protection Corporations: The Life and Non-life Policyholder Protection Corporations (PPCs) are mandatory policyholder protection systems created to provide capital and management support to insolvent insurers. Legislation was introduced in Japan's Diet in late 2008 to renew the life insurance PPC system prior to its scheduled expiration in April 2009. The new legislation, which passed the Diet in December 2008, will renew the protection system for three additional years. It was passed without full deliberations on the effectiveness of the current system, which continues to rely on pre-funding of the PPC by its members and a government "fiscal commitment" in case industry funding is insufficient, instead of adopting a system where an insolvency would result in members contributing funds to the PPC as needed (post-funding). The U.S. Government continues to urge Japan to consider more fundamental changes in the PPC systems, including through full and meaningful deliberations with interested parties before renewal legislation is required.

Bank Sales: In December 2007, the Japanese government fully liberalized the range of insurance products eligible for sale through banks. As a follow-up, the U.S. Government promptly asked Japan to review market conduct rules, including the limits on sales of first and third sector products and treatment of customer data (including Insurance Business Law Enforcement Rules, Article 212), to ensure they do not limit the effectiveness of bank sales of insurance or impede consumer convenience and choice.

Professional Services

Medical Services: Restrictive regulation limits foreign access to the medical services market. The U.S. Government has continued to urge Japan to open new opportunities for commercial entities to provide full-service, for-profit hospitals, including through Japan's special economic zones, in order to open this sector to foreign affiliated providers.

Educational Services: Excessive regulation related to both administrative requirements and restrictions on pedagogical choices has discouraged foreign universities from operating branch campuses in Japan. Under the United States-Japan Investment Initiative, the Japanese government established a new category of "Foreign University -- Japan Campus" for foreign accredited institutions of higher education. While this designation provides these campuses with benefits similar to those accorded Japanese educational institutions (*e.g.*, student eligibility for student rail passes and student visas), it does not confer the tax benefits enjoyed by Japanese institutions and their students. The U.S. Government continues to urge Japan's Ministry of Education, Culture, Sports, Science and Technology to work with these foreign

universities to find a nationwide solution that grants tax benefits comparable to Japanese schools and allows them to continue to provide their unique contributions to Japan's educational environment.

INVESTMENT BARRIERS

Despite being the world's second-largest economy, Japan continues to have the lowest inward foreign direct investment (FDI) as a proportion of total output of any major OECD country. Inward foreign mergers and acquisitions (M&A) activity, which accounts for up to 80 percent of FDI in other OECD countries, also lags in Japan, even though it has been on an upward trend.

The Japanese government has recognized the importance of FDI to revitalizing the country's economy. In September 2006, the Japanese government set a goal of doubling the stock of FDI in Japan by 2010 to the equivalent of 5 percent of Gross Domestic Product (GDP). Japan has also taken several recent steps to improve the FDI environment, including revision of the Corporate Code to permit the use of triangular stock swaps for international M&A deals. With only one cross-border stock transaction occurring under the new rules, however, the adequacy of measures taken to date to promote cross-border M&A rules remains unclear. Cross-border M&A is more difficult in Japan than in other countries, partly because of attitudes toward outside investors, inadequate corporate governance mechanisms that protect entrenched management over the interest of shareholders, and a relative lack of financial transparency and disclosure.

The United States-Japan Investment Initiative, initiated in 2001 and co-chaired by the U.S. Department of State and Japan's Ministry of Economy, Trade and Industry, has worked to promote policy changes that improve the overall environment for foreign (and domestic) investment and to focus on specific barriers in certain sectors, including educational and medical services.

OTHER BARRIERS

Automobiles and Automotive Parts

A variety of nontariff barriers have traditionally impeded access to Japan's automobile and automotive parts market, and overall sales of North American made vehicles and parts in Japan remain low. The Japan Automobile Importers Association (JAIA) reports that sales of U.S. produced motor vehicles in Japan were 15,341 units in 2007. During the past year, U.S. automakers also have significantly divested their holdings in Japanese automobile manufacturers.

Through the Regulatory Reform Initiative, the U.S. Government has continued to address crosscutting structural and regulatory reform issues with Japan that affect the automotive sector, including urging Japan to take steps that strengthen competition policy and increase transparency in rule making. It is also important for Japan to take into full consideration global harmonization efforts as it develops and implements regulations.

Aerospace

Japan is among the largest foreign markets for U.S. civil aerospace products. The civil aerospace market in Japan is generally open to foreign firms and some Japanese firms have entered into long-term relationships with American aerospace firms. The U.S. Government continues to monitor Japan's development of indigenous civil aircraft.

Military procurement by the Ministry of Defense (MOD) accounts for over half of the domestic production of aircraft and aircraft parts and continues to offer the largest source of demand in the aircraft

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industry. Although U.S. firms have frequently won contracts to supply defense equipment to Japan (over 90 percent of the annual foreign defense procurement is from the United States), the MOD has a general preference for domestic production or the licensing of U.S. technology for production in Japan to support the domestic defense industry.

Although Japan has considered its main space launch vehicle programs as indigenous for many years, U.S. firms continue to participate actively in those space systems, including Japan's primary space launch vehicle, the HII-A. The U.S. Government has welcomed Japan's plans to develop a supplementary GPS navigation satellite constellation known as the "quasi-zenith" system. The U.S. Government is working closely at the technical level with Japanese counterparts to ensure the Japanese and U.S. systems remain compatible and anticipates U.S. companies will have the opportunity to supply major components.

Business Aviation

Japan's regulatory framework coupled with infrastructure shortages impedes the development of business aviation in Japan. Because of the lack of guidelines specific to business aviation, regulations for commercial airline safety, maintenance, and repair issues administered by the Japan Civil Aviation Bureau (JCAB) of the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) also apply to business aircraft. This situation in turn raises the costs of qualification, operation, and maintenance of business aircraft to uneconomical levels and leads to most business aircraft operating in Japan being registered in the United States. In addition to the regulatory environment, landing rights for business aircraft in Japan are difficult to obtain because of rules that hamper flexible scheduling, especially in the Tokyo area. These factors greatly limit business opportunities in this sector for sales of U.S. aircraft in Japan.

Certain Chubu and Kansai region airports have begun to attract business aircraft, although with modest results thus far. Regional airports are attempting to provide many of the same services business aircraft operators receive in the United States and Europe. Severely restricted hours for landings and take-offs at Haneda Airport in Tokyo, a preferred business destination, and the lack of services for private business aircraft at both Narita and Haneda continue to significantly limit travel to and within Japan.

The U.S. Government has continued to urge JCAB to reexamine the application of airline-specific commercial civil aviation regulations to business aviation and develop appropriate regulations specific to the business aviation industry that are consistent with the treatment of business aviation in North America, Europe, and other developed economies. Immediate improvements in the overall regulatory framework for business aviation are needed in advance of an additional runway opening at Haneda planned for 2010.

During 2008, the JCAB took some initial and positive steps, including engaging in greater dialogue with the U.S. Government and other stakeholders. A May 2008 JCAB report highlighted the importance of business jets in Japan's aviation future and noted that Japan lags noticeably behind other countries in business aviation development. The JCAB also laid out a road map for a new business aviation policy, calling for improvements in facilitation, regulatory framework, facilities, and air fields. In July 2008, in its first actual deregulation involving business aviation, JCAB extended its ETOPS (Extended-range Twin-engine Operational Performance Standard) requirement from 60 minutes to 180 minutes, which permits JA (Japan) registered aircraft with two engines to fly routes far longer than they could previously.

Civil Aviation

Consistent with its longstanding policy to promote competition and market access in civil aviation, the U.S. Government continues to press Japan for further liberalization. Market access for U.S. air carriers in Japan improved significantly with a 1998 bilateral agreement and additionally with a new bilateral agreement in September 2007 (being applied pursuant to comity and reciprocity pending formal conclusion). U.S. carriers, however, remain constrained by restrictions on traffic rights, operational flexibility, change-of-gauge, and pricing. Other key concerns include the continuing disparity between the rights of "incumbent" and "non-incumbent" airlines, and some of the world's highest airport costs.

The September 2007 agreement provides non-incumbent cargo carriers the ability to serve additional points in Japan and beyond. It also removes many restrictions and limitations on same-country code-sharing arrangements, but such opportunities remain more limited than the open code-sharing framework in U.S. agreements with most other countries. The delegations also stated their intention to relax the pricing regime from "double approval" to "country of origin." This is short, however, of the standard "double disapproval" regime for pricing liberalization. U.S. industry has expressed concern that Japan requires cumbersome and time-consuming filings for fare changes.

Tokyo's Narita International Airport operates below its potential capacity. The U.S. Government continues to encourage Japan to take steps to increase capacity and reduce congestion at one of the world's most important airports. An extension of Narita's second runway that will facilitate more long-haul flights is currently underway, although concerns remain about the project's financing and specifically that already high user fees might be increased. Recently lowered landing fees at Narita were offset in part by the imposition of other new or increased fees. The U.S. Government continues to raise the issue of high landing fees at Narita, Kansai, and Central Japan International Airport (Centrair) airports in the Regulatory Reform Initiative and other bilateral discussions.

Both Narita and Haneda Airports are undergoing ambitious expansion projects set to be completed in 2010. However, the planning process for both these projects has not been fully transparent. U.S. carriers have expressed serious concerns about how new slots at Narita Airport will be allocated and with the unfair advantage that Japanese carriers would enjoy if slots at Haneda were allocated for service to the United States in the restricted night hours that MLIT's most recent plans envision. These issues are properly addressed in bilateral air transport negotiations. Separately, the U.S. Government notes that connections between airports in the Tokyo metropolitan area remain difficult and time-consuming, and that the weak connectivity undermines the efficiency of the airports and carriers serving Tokyo. The U.S. Government is encouraged by improvements that are now under consideration within MLIT to improve transit access between Haneda and Narita airports.

Transport/Ports

The U.S. Government continues to raise longstanding concerns about barriers to entry to, and the competitiveness of, Japanese ports. Foreign shipping companies servicing Japan are locked into long-term relationships with specific Japanese stevedoring companies, which reportedly collude within the industry association to keep newcomers out and costs high. Foreign companies are concerned that a lack of transparency in Japanese laws and regulations related to ports creates a barrier to entry. Stevedoring businesses owned and run by foreigners do not exist at major Japanese ports. As part of the Regulatory Reform Initiative, the U.S. Government has made recommendations on transparency that are applicable to the rulemaking process. Japanese laws and regulations could be reviewed to facilitate new entrants and greater competition in the stevedoring business.

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Japan amended its Port Transportation Business Law (effective November 2000) to eliminate the need for new entrants to prove the existence of surplus demand. Charges for harbor services in nine large ports are subject to a prior notification requirement, and there is an approval requirement for other ports by MLIT.

Since 1999, the U.S. Government has continued to express concern that reforms have not lessened the Japan Harbor Transportation Association (JHTA)'s ability to inhibit new entry and restructuring in the ports sector. The Port Transportation Business Law introduced requirements that run counter to the need for efficient port operations and discriminate against new entrants wishing to offer port services. In addition, MLIT has not addressed concerns about the prior consultation process conducted by the JHTA nor about the apparent threat of illegal strikes against foreign carriers who obtain permission to operate their own container terminals. The U.S. Government has raised with the Japanese government its failure to implement important aspects of the wide-ranging port deregulation promised in 1997. The U.S. Government is continuing to encourage Japan to share further information about changes in Japanese law made in 2006 that may be relevant to the FMC's ongoing review of conditions at Japanese ports.

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